# OR Petition 7



# Raleigh Orthopaedic Clinic, PA Petition for Need Determination for Six Orthopedic Ambulatory Surgery Operating Rooms in Wake County Playing Section

#### **EXECUTIVE SUMMARY**

Each year, the State Health Coordinating Council publishes a Proposed State Medical Facilities Plan and then holds public hearings and receives petitions for special need determinations for regulated healthcare services. Raleigh Orthopaedic Clinic (ROC) has serious concerns that the Proposed 2008 Plan includes no additional operating rooms for Wake County. In fact, no additional operating rooms have been allocated to Wake County by the Plans in over ten years.

Raleigh Orthopaedic Clinic petitions for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers in Wake County.

ROC physicians know that an orthopedic ambulatory surgery center (ASC) can offer patients exceptional quality and customer service, lower costs, more efficient scheduling and better teamwork. The American Academy of Orthopaedic Surgeons states "ASCs provide benefit to both patients and orthopaedic surgeons because many musculoskeletal surgical procedures can be provided in an efficient, cost effective manner. ASCs can improve the quality of care received by the patients and delivered by the physician."

The rationale for the ROC petition is summarized:

- Wake County has 9.93 operating rooms per 100,000 population, far less than comparable counties and 22 percent less than the statewide rate of 12.75 ORs per 100,000 persons.
- ASCs generally have greater scheduling efficiency and higher patient satisfaction as compared to hospitals. While 73 percent of all surgery cases are ambulatory, 89 percent of the operating rooms in Wake County are hospital-based.
- In 2006, over 6,000 Wake County patients obtained ambulatory surgery in another county; more ambulatory surgery patients left Wake County in 2006 as compared to Mecklenburg and Forsyth Counties.
- No dedicated orthopedic ambulatory surgery operating rooms exist in Wake County even though orthopedic ambulatory surgery procedures comprise 23 percent of the total outpatient cases.
- Orthopedic procedures performed in freestanding ambulatory surgery centers offer 30 to 40 percent lower charges and reimbursement rates.
- ROC physicians have already established exemplary records for providing charity care in their offices and at the area hospitals.

Approval of the petition will <u>benefit the community</u> by allowing new providers to compete and improve access to dedicated orthopedic ambulatory surgery operating rooms. The ASC will offer greater convenience, higher patient satisfaction and lower costs and charges. Like hospitals, the proposed ambulatory surgery center will be licensed, accredited and required to provide care to Medicare, Medicaid, insured patients and charity care patients.

#### **PETITION**

TO:

Medical Facilities Planning Section

**Division of Facility Services** 

701 Barbour Drive

2714 Mail Service Center Raleigh, NC 27699-2714

PETITIONER:

Karl Stein, Executive Director Raleigh Orthopaedic Clinic 3515 Glenwood Avenue Raleigh, NC 27612

919 863-6801

DATE:

July 31, 2007

RF:

Petition for Need Determination for Six Orthopedic Ambulatory

Surgery Operating Rooms in Wake County

#### Introduction

Raleigh Orthopaedic Clinic (ROC), with nineteen physicians, is the largest orthopedic practice in Wake County. ROC physicians have privileges at Rex Hospital and WakeMed (New Bern and North locations). The group has four office locations and serves patients from all of Wake County and a large region of eastern North Carolina. In 2006, ROC physicians performed over 7,300 orthopedic surgical procedures; ambulatory surgery procedures comprised 76 percent of the total.

ROC physicians helped found and are active participants in the Wake County Medical Society's Project Access, which provides free office visits for low income patients. In addition, ROC physicians choose to provide healthcare services to uninsured and indigent patients including emergency department coverage and inpatient and outpatient consults and procedures. The ROC practice and its individual physicians pay property taxes and income taxes and generously contribute to a wide range of charities. ROC physicians are extremely involved in research, education, community agencies, and professional organizations. The estimated total value of the community benefits for their charitable professional services exceeds 1.2 million dollars per year when including Project Access, charity care, bad debt, and the individual physicians' financial contributions and professional time provided to schools, agencies and societies. Please see Attachment 1.

DESTINATION PROMING RECTIVED

Medical Facilities Planning Section ROC surgeons recognize that an orthopedic ambulatory surgery center (ASC) can offer patients exceptional quality and customer service, lower costs, more efficient scheduling and better teamwork. The American Academy of Orthopaedic Surgeons states that "ASCs provide benefit to both patients and orthopaedic surgeons because many musculoskeletal surgical procedures can be provided in an efficient, cost effective manner. ASCs can improve the quality of care received by the patients and delivered by the physician." The benefits of Ambulatory Surgery Centers (ASCs) are described in the articles in Attachments 2 and 3.

Orthopedic ambulatory surgery represents the <u>largest volume</u> of all the surgical specialties and offers a tremendous opportunity to improve patient satisfaction and cost savings. The need is great, because demand for orthopedic surgery to increase by at least four percent per year based on national statistics and even more based on the exceptional population growth rate for Wake County.

Raleigh Orthopedic Clinic has worked diligently through the regulatory process for several years in an effort to provide ambulatory surgery services to residents of Wake County. ROC has submitted three annual petitions to the State Health Coordinating Council for adjusted need determinations for ambulatory orthopedic operating rooms in Wake County. These previous petitions were denied. Earlier this year, ROC also made a formal presentation to the Operating Room Work Group regarding ways to improve the planning process and promote fairness. (Please see Attachment 4 for a copy of the presentation by Raleigh Orthopaedic Clinic, PA.)

The State Medical Facilities Plan has provided no need determinations for additional surgical operating rooms in Wake County in the past five years. Therefore new providers have been precluded from submitting CON applications to construct new surgical facilities. However, during this same time period, Wake County hospitals found several inventive ways to add surgical capacity and establish new facility locations including:

- Converting and relocating existing endoscopy procedure rooms to become surgical operating rooms
- Relocating existing operating rooms to develop new satellite facilities that are "extensions" of the hospital
- Adding dedicated C-section operating rooms
- Converting C-section rooms to surgical operating rooms
- Adding minor surgery "procedure rooms" (these are rooms within the hospital that are not built or equipped to the same construction standards as a licensed surgical operating room and are not CONapproved)

For years the hospitals in Wake County have increased their surgery capacity (even though no need for additional licensed ORs appeared in the State Plan) and have blocked the entry of any new surgical provider that could provide more cost effective ambulatory surgery. The Proposed 2008 State Medical Facilities Plan shows a projected surplus of <u>0.79</u> operating rooms in Wake County. This small surplus of operating rooms means no need exists for new surgical operating rooms in Wake County.

ROC contends that the current operating room methodology does not accurately assess the future needs of the population or recognize the limitations of the operating rooms in Wake County. The OR methodology also omits the surgery volume that has been shifted to the minor surgery procedure rooms. If these surgery cases were properly included in the demand calculations, Wake County would then show a need for additional full service operating rooms.

Raleigh Orthopaedic Clinic petitions for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

#### II. Rationale for the Proposed Changes

The current OR methodology in the Proposed 2008 State Medical Facilities Plan does not accurately assess the ambulatory surgery operating room needs of Wake County:

- No dedicated orthopedic ambulatory surgery operating rooms exist in Wake County even though orthopedic ambulatory cases comprise 23 percent of the total outpatient cases. Orthopedic procedures performed in freestanding ambulatory surgery centers offer substantially lower costs, charges and reimbursement for insured patients and Medicare and Medicaid programs. Cost savings result in lower out-of-pocket costs for patients and lower payments / less expense to the payors. Please see Attachment 6.
- 2 The current methodology and CON process has allowed existing Wake County providers to add many "minor procedure rooms" to perform surgical cases. These procedure rooms are not constructed or equipped to the same standards as licensed operating rooms. Shifting surgery cases from licensed operating rooms to the minor procedure rooms does not promote access to quality healthcare. Please see Attachment 7.
- Minor surgery procedure room cases (including some procedures requiring general anesthesia) are not counted in the OR methodology even though the same types of cases performed in these procedure rooms in Raleigh hospitals are often performed in licensed operating rooms at hospitals elsewhere in the State. Shifting surgery cases out of the licensed operating rooms suppresses the growth in total surgery utilization in the OR methodology and postpones the need to add licensed operating rooms

- through need determinations. This miscounting of cases is particularly bad in Wake County because there are so many minor procedure rooms in use.
- 4 The operating room methodology is skewed by the erroneously reported hours and days of operation in the Wake County hospital license renewal applications. Few operating rooms where scheduled procedures are performed are actually staffed beyond eight hours per day. For planning purposes the hours of utilization for C-sections and emergency trauma cases should be excluded from the hours-of-operation calculations. The operating rooms where ambulatory orthopedic surgery cases can be scheduled are available Monday through Friday only and all of the ambulatory and shared rooms (inpatient and ambulatory) are closed on major holidays. The assumption that scheduled surgery cases are performed 260 days per year in Wake County is wrong; a more realistic figure is 255 days.
- Open heart services and heart lung bypass equipment at WakeMed and Rex Hospitals function at less than 40 percent of capacity (see page 80 of the Proposed 2008 Plan). Averaging less than one case per room per day, these dedicated open heart inpatient operating rooms are not available for any type of ambulatory surgery. The operating room inventory for Wake County includes the <u>four dedicated open heart operating rooms at WakeMed</u> that are underutilized. During the previous year, the four open heart rooms at WakeMed performed a total of 931 cases. If these four dedicated open heart rooms and associated cases were excluded from the operating room need calculation, even with no other changes to the methodology, Wake County would show a deficit of two operating rooms as seen in Attachment 5. Rex has operating rooms used exclusively for cardiovascular surgery, although it does not classify them for regulatory purposes as dedicated open heart operating rooms. If these rooms and cases were excluded the deficit would be even higher.
- 6 Hospitals generally have lower surgery scheduling efficiency and lower patient satisfaction as compared to ambulatory surgery centers. Please also see Attachment 8 for data regarding hospital acquired infections. Based on these circumstances, patients need improved access to freestanding ambulatory surgery centers.
- 7 Existing surgery resources (licensed ORs and "procedure rooms") in Wake County are inadequate to meet the needs of orthopedic ambulatory surgery patients. Patient origin data demonstrates that thousands of Wake County patients are leaving their home county to obtain ambulatory surgery in other counties. Please see the chart on page 5. This requires patients to travel in the darkness, while hungry, after sedation, and while in pain. Some caregivers are confronted with extended travel distances while simultaneously attending to their patient needs. And when problems arise, the on-call physicians in the local hospital are unfamiliar with the circumstances of the out-of-town surgery.

- 8 ROC physicians have already established exemplary records for providing charity care in their offices and in the hospital (in addition to providing uncompensated on-call coverage for emergency patients). ROC suggests that the CON applications for the proposed additional orthopedic ambulatory operating rooms be required to meet a defined minimum percentage and dollar amount for charity care. Please see the letters in Attachment 9.
- 9 ROC is petitioning (for the fourth time) for ambulatory orthopedic operating rooms to fulfill the needs of Wake County and to overcome the limitations and obstacles posed by the present OR methodology and CON regulations. The ROC petition has extensive community support as seen in Attachment 10.

The following analysis explains the unique characteristics of Wake County and the problems with the 2008 OR methodology:

# <u>Lack of Adequate Access to Ambulatory Operating Rooms in both North Carolina and Wake County</u>

North Carolina has a total of 49 freestanding ambulatory surgery centers. Nearby, South Carolina and Tennessee, both with smaller populations, have 56 and 128 ASCs respectively. Most states with similar size populations have far more ASCs:

Ohio 168 Georgia 204 New Jersey 166 Washington 197

While 25 states have no CON regulations, many of the remaining CON states have exemptions from CON review for single specialty ASCs or separate and streamlined CON / licensure processes.

Within North Carolina, Wake County citizens have access to fewer operating rooms per 100,000 population than other comparable counties and the overall North Carolina population. The OR Planning Inventory statistics from the Proposed 2008 State Medical Facility Plan are examined and compared on a per capita basis compared as follows:

2005-06 Operating Room Data	Number of Licensed Surgery Providers (All Facililies)	2008 OR Planning Inventory - Total Number of Licensed ORs	2010 Projected Population	ORs per 100,000 (Excluding Chronically Underutilized ORs. C- Section and Trauma Rooms)
Wake County	9	90	906,800	9.93
Mecklenburg	13	146	930,663	15.69
Forsyth	5	83	351,864	23.59
North Carolina	171	1209	9,485,138	12.75

Sources: Draft 2008 SMFP

OR Planning Inventory based on Column S page 67 - 68

(Excludes ORs in Chronically Underutilized Facilities, C-Section Rooms and Trauma Rooms)

North Carolina State Demographics (Updated in June, 2007)

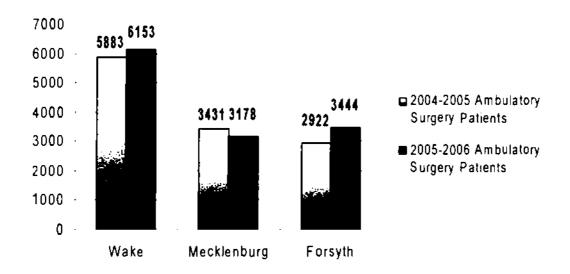
Wake County has fewer surgery facilities and fewer licensed operating rooms per capita as compared to Mecklenburg and Forsyth Counties as well as to the overall North Carolina population.

"North Carolina and particularly Wake County now lag behind many other metropolitan areas in terms of the availability of specialized ambulatory surgery operating rooms. Wake County patients deserve access to state-of-the-art orthopedic ambulatory surgery operating rooms. These operating rooms will be specially equipped and staffed by highly trained surgical teams adept at performing the highest quality orthopedic procedures."

#### Robert Wyker, MD

The lack of an adequate number and types of surgical operating rooms restricts access for patients and surgeons in Wake County. The number of Wake County patients that leave their home county to obtain ambulatory surgery procedures at facilities in other counties is another measure of the shortage of operating rooms.

# Number of Patients Obtaining Ambulatory Surgery Procedures Outside of Their Home Counties



Source: Division of Facility Services, Medical Facilities Planning Section, Patient Origin Data, 2004-05 and 2005-06.

Analysis of Data and Chart by Strategic Healthcare Consultants

Patient origin data demonstrates that thousands of Wake County patients are leaving their home county to obtain ambulatory surgery. The 6,153 statistic means that more than 12 percent of all the Wake County ambulatory surgery patients left their home county to obtain ambulatory surgery procedures in other counties. Thousands of patients leaving Wake County to obtain ambulatory surgery represent a huge quality concern. This situation should be remedied because: 1) it forces patients and their families to drive long distances in the pre-dawn traffic to surgery; 2) it discriminates against patients without transportation or financial means; 3) it prevents loved ones from being at the surgery because they cannot miss a whole day of work for the commute; 4) it forces the patient (now in pain and recovering from anesthesia) to travel to get back home after surgery; 5) it means late night problems must be handled by local emergency room doctors who are unfamiliar with the medical case; 6) it prevents continuity of care because the travel discourages adequate pre- and post-op follow up appointments.

Of these 6,153 ambulatory surgery patients that left Wake County to go to other facilities, ROC estimates 1,300 to 1,400 (20 to 25 percent) were ambulatory orthopedic surgery cases. Approval of the ROC petition will improve access to ambulatory orthopedic surgery and reduce the need for Wake patients to leave their home county to obtain surgery.

## Orthopedic Ambulatory Surgery Represents the Largest Component of Ambulatory Surgery in Wake County

In 2006, ambulatory orthopedic surgery cases performed in Wake County totaled 12,884 cases or 23 percent of the total ambulatory surgery volume. Orthopedic ambulatory surgery represents the largest volume of procedures and thus the greatest opportunity for substantial cost savings for patients and the healthcare system. The next table shows the 2005-06 ambulatory surgery volume by specialty category and by facility.

Wake County Ambulatory Surgery						Raleigh	Raleigh	Southern		
Cases Performed in Licensed	WakeMed					Plastic	Women's	Eye		
Operating Rooms	Raleigh All	WakeMed Cary	Rex	Duke Health	Health South	Surgery	Health	Associates	TOTAL	% of Total
Cystoscopy	602	0	27	0	0	0	0	0	629	1%
Endoscopy	15	0	8	41	0	0	0	0	64	0%
General	2.739	2.629	3.740	2.651	0	O	0	0	11.759	21%
Gynecology	1.607	1.480	2.587	314	0	0	3.100	0	9.088	16%
Neurosurgery	700	0	493	192	0	0	0	0	1.385	2%
Open Heart	0	0	0	0	0	0	0	0	0	0%
Ophthalmology	764	516	670	547	0	0	0	487	2.984	5%
Oral Surgery	1.085	201	13	9	10	0	0	0	1.318	2%
Orthopedics	2.557	708	3.589	3.962	2,068	0	0	0	12.884	23%
Otolaryngology	2.227	836	3.108	0	2,446	0	0	0	8.617	15%
Plastic Surgery	259	128	2.366	337	1	371	0	0	3,462	6%
Podiatry	207	0	401	1	530	0	0	G	1.139	2%
Thoracic	9	17	4	0	0	0	0	G	30	0%
Urology	826	254	804	101	0	0	0	0	1,985	4%
Other	33	1	412	0	0	0	0	0	446	1%
TOTALS	13.629	6.770	18.222	8,155	5,055	371	3.100	487	55.789	100%

(The above volumes do not include the hundreds of hand surgery, ophthalmic surgery and pain procedures that previously were performed in licensed ORs but recently have been shifted to the minor procedure rooms that do not meet full licensure <u>standards for operating rooms</u>.)

No facility in Wake County has even one <u>dedicated</u> ambulatory orthopedic surgery operating room.

Multi-specialty operating rooms are a concern because with the mix of different surgical specialties the equipment and staff to have to be changed throughout the day. This causes extended between-case set-up and cleaning times and detracts from overall efficiency. Multi-specialty shared operating rooms are most likely to have schedule delays due to the ill-assorted medley of inpatient and outpatient cases of varying specialties and equipment set up requirements.

HealthSouth Blue Ridge Surgery Center is the only freestanding (non-hospital) ambulatory surgery center where ambulatory orthopedic cases are performed; it has six multi-specialty ambulatory operating rooms.

The only dedicated ambulatory surgery licensed operating rooms in Wake County are listed as follows:

Raleigh Plastic Surgery Center Inc. (Plastic Surgery)
Raleigh Women's Health Organization (Gynecology)
Southern Eye Associates Ophthalmic Center (Ophthalmology)

Each of the above single specialty ambulatory surgery centers represents a specialty with lower volumes and percentages of the total ambulatory surgery demand than orthopedic surgery. And while two of these facilities are underutilized, none of these single specialty operating rooms can be used to perform orthopedic surgery. Single specialty ambulatory surgery centers must obtain CON approval to add a new surgical specialty even if the proposed change has zero capital cost. Also, these ASC facilities were not constructed to current OR standards for orthopedic cases. Based on these circumstances, ROC is convinced that none of the existing single specialty ambulatory surgery centers can support orthopedic surgery.

Wake County does have four dedicated open heart operating rooms, all located at WakeMed; Rex Hospital provides open heart surgery in rooms dedicated to cardiovascular surgery but not so designated with the state. Over the past decade, open heart surgery procedures in Wake County have declined 10 percent from a combined total of 1,673 cases in 1998 down to 1,490 in 2006. Page 80 of the Proposed 2008 Plan shows that heart-lung bypass units are underutilized across the state. In Wake County, the 1,490 open heart surgery cases represent less than two percent of the total surgery volume and yet dedicated open heart rooms remain in the OR need methodology calculation. If these four dedicated open heart rooms and associated cases were excluded from the operating room need calculation, even with no other changes to the methodology, Wake County would show a deficit of two operating rooms as seen in Attachment 5.

#### Existing Resources are Inadequate and Ineffective

The population of Wake County is projected grow by 16.8 percent or 138,266 persons over the next five years. Raleigh population growth has outpaced every other NC metropolitan service area. To accommodate this growth, numerous major transportation improvement projects are ongoing and seven new schools are being built. The petitioner is convinced that the incredible population growth of Wake County will continue to surpass the capacity of the existing operating rooms. Furthermore, the present allocation of operating rooms (that are primarily hospital-based) is outdated and incredibly inefficient, as illustrated by the dedicated open heart operating rooms that have experienced consistent declines in utilization.

Outpatient surgery will continue to comprise the majority of all surgery. Orthopedic surgery already represents the largest percentage of ambulatory surgical utilization and is projected to experience strong growth in outpatient demand due to changes in technology, physician recruitment and the growth and aging of the population. The existing Wake County hospitals and facilities have been ineffective at improving ambulatory surgery access and quality of care as follows.

- Many of the existing inpatient, ambulatory and shared operating rooms in Wake County are too small to be properly prepared for specialized orthopedic procedures. The inadequately sized rooms take longer to set up with equipment and to clean between cases.
- Multi-specialty operating rooms often require changes to the surgery schedule, the room set-ups and the staffing assignments. This daily juggling act of operating rooms, equipment and staff delays procedures, increases labor costs and frustrates surgeons.
- Wake County's existing surgical providers are unwilling to add or develop dedicated orthopedic operating rooms. ROC surgeons believe that the lack of dedicated orthopedic rooms increases the risk of incidents and complications.
- 4. Over the years, the hospitals have been dispersing operating rooms and emergency departments to establish new facilities. Orthopedic surgeons find it increasingly difficult to obtain additional operating room time at any one surgical facility.
- 5. Wake County hospitals that have developed minor surgery "procedure rooms" have gained surgery capacity that is less effective than licensed and fully functional operating rooms. In fact the hospitals' license renewal forms document that these minor procedure rooms are "not equipped or meeting all the specifications for an operating room..." Neither the specific physical limitations nor the billing rates for these minor surgery procedure rooms are publicly disclosed in the hospital license renewal applications. Please see Attachment 7 for additional documentation.
- Hospital patients are increasingly at risk for hospital acquired nosocomial infections as documented in Attachment 8. Nosocomial infection risks are lower at ASCs.

Approval of the petition for six (6) dedicated orthopedic ambulatory surgery operating rooms will promote positive competition and improve quality in Wake County. ROC is committed to construct ambulatory orthopedic rooms that meet or exceed the local, state and federal OR construction and accreditation standards.

## Cost Savings for Ambulatory Surgery Centers (ASCs) as Compared to Hospital Outpatient Surgery

There are huge cost savings related to ambulatory surgery procedures performed in freestanding ASCs as compared to hospital outpatient surgery. The Centers for Medicare and Medicaid announced plans to expand the range of services for which ASCs will be paid a facility fee. It will pay ASCs a projected 62% of outpatient procedure fees paid to hospitals. (Please see Attachment 6.) Medicare coinsurance rates are significantly lower for ASCs as compared to hospital outpatient departments.

The following chart compares the Medicare 2008 HOPPS (Hospital Outpatient Prospective Payment System) rates paid to hospitals with the 2008 ASC payments for a few frequently performed types of orthopedic ambulatory procedures.

CPT/ HCPCS	Short Description	HOPPS 2008 Rates	Estimated CY 2008 Fully Implemented Payment	ASC Payment as Percentage of HOPPS Payment
23107	Explore treat shoulder joint	1867.88	1069.09	57.2%
26020	Drain hand tendon sheath	1071.44	687.24	64.1%
29825	Shoulder arthroscopy/surgery	1875.55	1217.77	64.9%
29876	Knee arthroscopy/surgery	1875.55	1217.77	64.9%
29887	Knee arthroscopy/surgery	1875.55	1217.77	64.9%

Even with these huge cost savings, the petitioner expects that Wake hospitals will complain that shifting orthopedic surgery cases from the hospital to a dedicated ASC will cause financial hardship for the hospitals and diminish their ability to provide indigent care. ROC points out that the three hospital systems in Wake County are among the wealthiest nonprofit healthcare systems in North Carolina. Nonprofit organizations have been granted enormous tax exemptions, and some receive multi-million dollar government subsidies for indigent care. Nonprofit hospitals across the country are being questioned as to whether their charitable contributions to the community measure up to the benefits of their tax exempt status.

ROC is convinced that approval of this petition will give a new ASC provider and a for-profit entity an opportunity to prove their willingness to provide charity care, expand access and pay taxes. If the State Health Coordinating Council has concerns about charity care related to ambulatory surgery centers, a change in the regulatory standards can be implemented that requires applicants to provide charity care at or above the level of the existing surgery providers. Please see Attachment 9 for additional data, regulatory recommendations and a commitment by Raleigh Orthopaedic Clinic to expand charity care.

#### Orthopedic Ambulatory Surgery Operating Rooms

Several trends are making orthopedic surgery move to the outpatient setting quicker than other specialties.

Anesthetic techniques including oxygen saturation monitoring, EEG monitoring of consciousness, new short-acting drugs, and new drug-reversal agents have made outpatient surgery very safe. At the same time, better cardiovascular health in the growing elderly population has vastly increased the need for orthopedic procedures.

Miniaturization of orthopedic instruments and implants is making it possible to perform an ever widening variety of orthopedic procedures on an outpatient basis. Many procedures that once required an incision are now performed percutaneously.

Regional anesthetic techniques have made inpatient orthopedic surgery much less common. These include techniques that:

- numb the arm or leg without putting the patient to sleep
- reduce cardiovascular stress on the patient and make post-op observation shorter
- allow larger surgeries to be performed at an outpatient center.
- numb the arm or leg for 6-12 hours

Raleigh Orthopedic Clinic surgeons now perform a sufficient volume of ambulatory surgery cases to easily support the full-time utilization of <u>six</u> ambulatory surgery operating rooms. In addition, ongoing physician recruitment by ROC will increase future ambulatory surgery utilization.

Ambulatory surgery operating rooms that are specifically designed, equipped and staffed for orthopedic procedures offer the most effective option for improving patient satisfaction and quality, reducing the risk of infection, and providing cost effective healthcare services. These are sometimes called "focused factories" by healthcare experts. The current standards for operating room design state that dimensions of up to 30 x 30 ft are needed to accommodate specialized orthopedic procedures. Few existing operating rooms in Wake County measure up to this standard.

The current Certificate of Need regulation for surgical operating rooms, 10A NCAC 14C .2106 (d), is provided as follows: "In competitive reviews, an applicant proposing to perform ambulatory surgical procedures in at least three specialty areas shall be considered more favorably than an applicant proposing to perform ambulatory surgical procedures in fewer than three specialty areas."

Based on this regulation, Raleigh Orthopaedic Clinic believes that if the standard OR methodology ever shows a need for any additional operating rooms in Wake County, there would be no chance for an orthopedic (single specialty) ambulatory surgery center to obtain CON approval. Petitioning for a special need determination for up to six orthopedic ambulatory surgery operating rooms best responds to the need in the community and would negate this biased regulation.

#### ROC Analysis of Wake County Operating Rooms and Procedure Rooms

The petitioner calculated the need for six additional operating rooms based on a review of the OR methodology in the 2008 Plan with two modifications:

One modification to the calculation is that the surgery procedures that were performed in the minor procedure rooms in 2005-06 are added back into the total surgery volumes for the licensed ORs. As seen in Step 2 of the table on the following page, thousands of cases have been diverted to the hospitals' procedure rooms. ROC believes that shifting surgery patients to a procedure room with limited capabilities does not improve access and undermines the planning process.

The second modification relates to the annual hours of operating room availability. ROC contends that the annual hours of availability for operating rooms should be based on 1836 hours (9 hrs per day, 255 days per year and 80% productivity) instead of 1872 hours. Most ambulatory and shared operating rooms in Wake County are closed for major holidays making these rooms available only 255 weekdays per year and not the 260 days currently used in the methodology.

		Inpatient		Combined	
	Wake County Operating Room Data and Inventory Information -	Cases minus C	Ambulatory	Inpatient plus	
	2008 Plan with ROC Recommended Changes	Section	Cases	Ambulatory	
1)	Wake County Operating Room Volumes (Proposed 2008 Plan)	21029	55789	76818	
2)	Add back in the surgery cases that were redirected to minor proc				
	Wake County Minor Procedure Room Surgery Cases				
	Rex Hospital Minor Procedure - Non GI Endoscopy Surgery Cases	44	4397	4441	
	WakeMed Minor Procedure - Non GI Endoscopy Surgery Cases	0	294	294	
	Total Cases with Minor Procedure Room Surgery Added	21073	60480	81553	
3)	Hours per case (same assumption as OR methodology)	3.0	1.5		
	Total Estimated Hours	63219	90720	153939	
4)	Population Growth Factor 2006-2010 (same assumption as OR n		0.1479		
	Total Surgical Hours Anticipated in 2010			176,707	
5)	ROC Recommended Hours per Room	<del> </del>		<del>                                     </del>	
	9 hrs per day / 255 days per year / 80%		-	1836	
6)	Projected Number of ORs Needed		_	96.2	
7)	Adjusted Planning Inventory for Wake ORs (same as OR methodology)				
8)	Projected Need for Additional ORs in 2010			6.2	

Steps 1, 3, 4 and 7 above are consistent with the data and assumptions in the OR methodology of the Proposed 2008 Plan. The changes to the methodology in Steps 2 and 5 are based on the <u>unique circumstances in Wake County</u> as described in this petition.

ROC also asserts that all six of the operating rooms need to be orthopedic ambulatory operating rooms because:

- 1 Orthopedics represents the largest volume and percentage of ambulatory surgery; no dedicated ambulatory orthopedic ORs exist.
- 2 Orthopedic surgery requires larger operating rooms to accommodate advanced technology.
- 3 Dedicated orthopedic ambulatory surgery operating rooms offer Wake County the greatest opportunity to improve quality of care, maximize efficiency and deliver substantial cost savings.

#### III. Requested Changes

The standard Operating Room methodology in the Proposed 2008 State Medical Facilities Plan does not adequately consider the unique characteristics of Wake County.

Raleigh Orthopaedic Clinic petitions for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

#### IV. Adverse Effects if the Changes Are Not Made

The expected adverse effects include:

- Wake County patients will be forced to travel to other counties for routine outpatient surgeries, which is unsafe for the patients, inconvenient for their families, and unfair to the Wake County physicians who are forced to provide emergency care for any complications.
- Wake County patients will be forced to pay for surgery at the higher hospital prices, instead of the lower price of a non-hospital ambulatory surgery center. Patients in this hospital-dominated market have little choice but to continue paying high hospital costs and deductibles for ambulatory surgery procedures that could be safely performed in an efficient, low-cost outpatient facility. This is especially harmful to patients because high-deductible insurance plans are becoming the norm.
- Wake County patients will experience delays and inconvenience in scheduling outpatient orthopedic surgery. Wake County orthopedic surgeons are working harder than ever in an inefficient system for scheduling and performing outpatient surgery. Population growth in the county will outpace the availability of operating room time making it increasingly difficulty to schedule patients for surgery in a timely manner.
- Wake County patients will have less access to operating rooms with consistent staffing and equipment. We feel that consistency in staffing and equipment makes orthopedic surgery safer in operating rooms dedicated to that type of surgery. In the current environment, consistency of staffing and equipment is getting less common. The number of ambulatory surgery operating rooms in Wake County is actually decreasing due to their conversion to shared operating rooms. As a result, the merged scheduling of outpatient cases with inpatient cases causes a higher percentage of procedures that are delayed or rescheduled. This causes difficulties for both patients and surgeons. Schedule delays decrease staff efficiency, diminish patient satisfaction, and can compromise quality of care.

- Wake County patients will have more surgery in hospital procedure rooms that are not equipped or designed to full operating room standards. It is uncertain if the surgery patients and the surgeons have been appropriately informed regarding the limitations of these minor surgery rooms. The need for hospitals to move surgery into these less-regulated procedure rooms would be reduced if this petition were approved to create more operating rooms in Wake County.
- Wake County will have fewer orthopedic surgeons to share the on-call coverage for emergency rooms. Restricted availability and inefficiency of in the current operating rooms make it increasingly difficult to recruit new orthopedic surgeons to Wake County. This county has a reputation for overcrowded and slow operating rooms. Existing operating rooms available to orthopedic surgeons are at high utilization. Also, surgeons state that they are twenty to thirty percent more productive in an ambulatory surgery center as opposed to a hospital surgery suite. Adjacent counties and states have more operating room availability and specialized orthopedic facilities. For these regions new surgeons prefer to locate in other communities without these problems. This limits the number of surgeons available to share in on-call coverage for emergency rooms for the rapidly growing population of Wake County.

#### V. Alternatives Considered

Maintaining the status quo is not an acceptable alternative because Wake County has high demand for orthopedic ambulatory surgery but limited operating room capacity. The standard OR methodology does not take into consideration the special characteristics of the service area. Projecting no need determinations for operating rooms encourages the development of more minor surgery procedure rooms that tack the equipment and facility characteristics of a fully licensed operating room. These procedure rooms are not constructed or equipped to meet the standards of licensed ORs. The physicians with Raleigh Orthopaedic Clinic are convinced that Wake County patients deserve access to a specialized facility that focuses on orthopedic surgical care.

Submitting a petition for an adjusted need determination for ambulatory surgery operating rooms in each of the six Health Service Areas is an option that was previously pursued without success. This alternative generated considerable discussion and members of the State Health Coordinating Council advised the petitioners to submit individual petitions for adjusted need determinations in specific service areas.

Submitting a petition for a need determination for multi-specialty ambulatory surgery operating rooms in Wake County is not an effective option because the need for specialized surgical capacity is most pronounced for orthopedic surgery.

As previously discussed, there are now more surgical specialists competing to book procedures in fewer multi-specialty ambulatory surgery operating rooms. Existing multi-specialty ambulatory surgery hospitals and facilities have fallen short with regard to providing consistent access and effective scheduling for orthopedic surgery cases. Orthopedic surgery typically requires larger operating rooms in order to accommodate the necessary equipment and special orthopedic operating tables.

The ROC petition request offers the most effective alternative to improve quality, expand access and deliver tremendous cost savings. An orthopedic ASC will help attract additional high-quality orthopedic surgeons who can then share in the charity work and on-call responsibilities. Orthopedic surgeons want the efficiency and consistent staffing that a dedicated orthopedic ASC will provide.

#### VI. Evidence That the Proposed Changes Would Not Result in Unnecessary Duplication of Health Resources

The following evidence is provided that the requested change will not result in unnecessary duplication of health resources:

- 1) The operating room inventory in the Proposed 2008 State Medical Facilities Plan shows no orthopedic (single specialty) ambulatory surgery operating rooms in Wake County. The requested orthopedic ambulatory operating rooms are not duplicative of the existing single specialty ambulatory surgery facilities for plastic surgery, gynecology and ophthalmology.
- Raleigh Orthopedic Clinic has confirmed that no CON applications have been submitted to add orthopedic surgery to the existing single specialty operating room facilities.
- 3) The petition for six orthopedic ambulatory surgery operating rooms does not duplicate the types of surgical operating rooms that are owned by the hospitals in Wake County. Hospital-based operating rooms are distinctly different because most are multi-specialty and the designation of the rooms (inpatient, ambulatory and shared) can be changed without having to obtain CON or other regulatory approval.
- 4) The ROC petition does not duplicate minor surgery "procedure rooms" that have been developed by hospitals as substitutes for a licensed operating room.
- 5) ROC is seeking what does not exist in Wake County dedicated orthopedic ambulatory surgery operating rooms that will be consistently focused on quality, patient satisfaction and cost effectiveness.

#### VII. Conclusion

Approval of this petition is justified because the proposal is consistent with the basic principals of the State Medical Facilities Plan regarding quality, cost effectiveness and improving access. The requested change for dedicated orthopedic ambulatory operating rooms in Wake County is based on a unique set of circumstances; the extraordinary population growth, the disparity in the number of licensed operating rooms per capita, the excessive number of ambulatory surgery patients that leave their home county, and the tremendous benefits in terms of cost savings and improved patient care.

Raleigh Orthopaedic Clinic intends to continue to push for changes in the State Medical Facilities Plan, the Certificate of Need regulations and the administrative rules related to operating rooms until the unique needs of Wake County can be met.

#### **Attachments**

- 1) Raleigh Orthopaedic Clinic Physician Involvement
- 2) Position Statement, Ambulatory Surgery Centers, American Academy of Orthopaedic Surgeons
- 3) Ambulatory Surgery Centers, A Positive Trend in Healthcare
- 4) ROC Presentation to the Operating Room Work Group
- 5) Calculations of Wake County OR Need Omitting Dedicated Open Heart Cases and ORs
- 6) Documentation Regarding Changes in Medicare Reimbursement
- 7) Hospital License Renewal Applications Showing Minor Surgery Procedure Rooms
- 8) Articles Regarding Hospital Infections
- 9) Commitment to Provide Charity Care
- 10) Community Support Letters

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#### **Attachment 2**



#### **Position Statement**

#### **Ambulatory Surgical Centers**

An Ambulatory Surgical Center (ASC) exclusively furnishes outpatient surgical services. There are currently more than 3700 Medicare-certified ASCs representing a doubling in the past decade. In 2001, ASCs supported 3 million surgical procedures and received about \$1.6 billion in Medicare payments. Notwithstanding this growth, ASCs accounted for less than 1 percent of total Medicare spending in 2001.

The number of ASCs has grown because of rapid advances in technology and medicine. The American Association of Orthopaedic Surgeons (AAOS), as one of the leading advocates for patient safety, believes that many procedures that were previously performed only in the hospital inpatient setting can now be safely performed in ASCs. For example, many orthopaedic procedures can be performed in ASCs because of advancements in arthroscopic equipment and techniques. The improvement of short-acting, general anesthesia has reduced operative and recovery times and has made it possible to perform more procedures in ASCs.

ASCs have also grown because they offer numerous benefits to the patient and the orthopaedic surgeon. For musculoskeletal patients, ASCs can be convenient because of shorter wait times before and after surgery. Furthermore, coinsurance rates are often lower when compared to other outpatient healthcare settings.<sup>3</sup>

Many musculoskeletal procedures are highly technical and specialized. ASCs allow orthopaedic surgeons to design a site where they can perform these complex procedures more efficiently than in other outpatient settings. For example, the operating room in an ASC is often customized for a specific procedure, such as arthroscopy. Equipment and supplies are setup for specific procedures, and the same clinical staff often works together on a daily basis. This makes it easier to schedule and perform surgery in an ASC, which can translate into improved efficiency, cost-effective use of resources, and better outcomes for patients.

The decision to perform procedures in an ASC should largely rest with physicians because they can assess the best venue for optimizing care. The physician would consider the anesthetic risk, age, and general medical condition of the patient; the expected duration and complexity of the operation; the anticipated degree of postoperative pain and discomfort; and the probability of complications. An operation would not be performed in an ambulatory setting – irrespective of convenience or cost – if the risk to the patient is increased. Improving the patient's quality of care and outcome should be the guiding principle in determining whether a procedure should be performed in an ASC.

Reimbursement for procedures performed in ASCs must adequately capture all labor, equipment, and supply costs required to operate an ASC. Furthermore, ASC payment systems should be designed so that they can react to changes in technology or prices. Medicare and private insurers must work closely with the ASC and physician community in order to ensure fair payment is received for services provided. Failure to do so can create problems. For example, although many implant procedures can be safely performed in ASCs, many payers do not reimburse for implant hardware. This is a serious problem because the implant device is often the costliest part of a procedure. The result is that

physicians cannot perform certain implant procedures in ASCs because reimbursement rates do not account for necessary costs, which are reimbursed in more expensive inpatient facilities.

The AAOS believes that many surgical procedures can be safely performed in ASCs. ASCs provide a benefit to both patients and orthopaedic surgeons because many musculoskeietal surgical procedures can be provided in an efficient, cost-effective manner. ASCs can improve the quality of care received by the patient and delivered by the physician. The growth and development of ASCs must not be hampered by restrictive payment or coverage policies from either Medicare or other private payers.

- 1. MedPAC Report to Congress, Medicare Payment Policy March 2003, p. 136.
- 2. MedPAC, p. 136
- 3. MedPAC, p. 140
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Document Number: 1161

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#### **Attachment 3**

# Ambulatory Surgery Centers

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#### A PROGRESSIVE MODEL FOR SURGICAL SERVICES

As our nation struggles with how to improve a troubled health care system, the experience of ASCs is a rare example of a successful transformation in health care delivery.

Thirry years ago, virtually all surgery was performed in hospitals. Waits of weeks or months for an appointment were not uncommon, and patients typically spent several days in the hospital and several weeks out of work in recovery. In many countries, surgery is still like this today, but not in the United States.

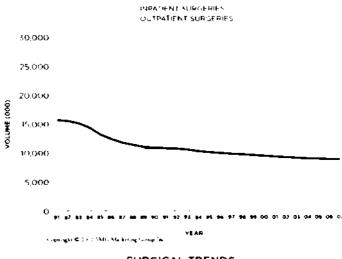
Physicians have led the development of ASCs. The first facility was opened in 1970 by two physicians who saw an opportunity to establish a high-quality, cost-effective alternative to inpatient hospital care for surgical services. Faced with frustrations like scheduling delays, limited operating room availability, and challenges in obtaining new equipment due to hospital budgets and policies, physicians were looking for a better way - and developed it in ASCs.

Physicians continue to provide the impetus for the development of new ASCs. By operating in ASCs instead of hospitals, physicians gain the opportunity to have more direct control over their surgical practices.\(^1\) In the ASC setting, physicians are able to schedule procedures more conveniently, assemble teams of specially-trained and highly skilled staff, ensure the equipment and supplies being used are best suited to their technique, and design facilities tailored to their specialties. Simply stated, physicians are striving for, and have found in ASCs, the professional autonomy over their work environment and over the quality of care that has not been available to them in hospitals. These benefits explain why physicians who do not have ownership interest in ASCs (and therefore do not benefit financially from performing procedures in an ASC) choose to work in ASCs in such high numbers.

Given the history of their involvement with making ASCs a reality, it is not surprising physicians continue to have ownership in virtually all (90%) ASCs. But what is more interesting to

note is how many ASCs are jointly owned by local hospitals that now increasingly recognize and embrace the value of the ASC model. According to the most recent data available, hospitals have ownership interest in 21% of all ASCs; 3% are owned entirely by hospitals.





SURGICAL TRENDS

OUTPATIENT SURGERIES
FREI STANDING OUTPATIENT SURGERY CENTER
PHYSICIAN OFFICE BASED SETTING

30 000

25,000

15,000

10,000

10,000

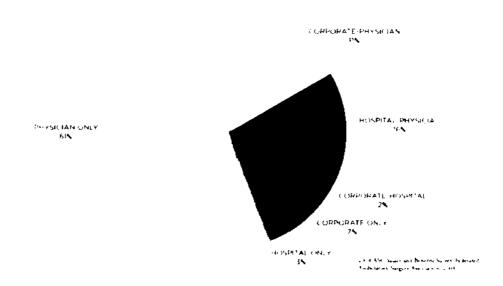
10,000

10,000

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VEAR

#### **ASC OWNERSHIP STRUCTURE**



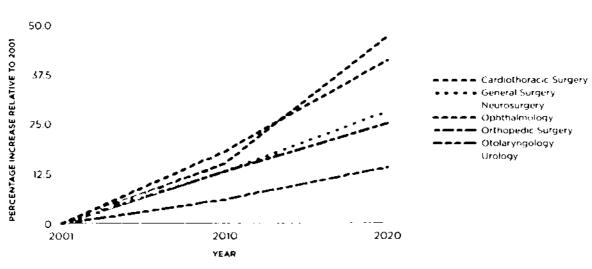
#### ASCS ALLOW PHYSICIANS TO WORK EFFICIENTLY

A recent analysis examined the impact of the aging population on the demand for surgical procedures and attendant need for surgical subspecialists. This study concluded that the aging population would be a major force in driving significant growth in the demand for surgical services. The forecasted growth in work by the year 2020 yarred from 14 percent to 47 percent, depending on specialty.\(^1\) Meeting these surgical needs will be a challenge. Solutions include increasing the number of surgical

residency positions, increasing the workloads of surgeons in the workforce, and improving the efficiency of surgeons.

Utilizing settings that allow physicians to practice efficiently will help mitigate the impact of the aging population on the anticipated shortage in the surgery workforce. ASCs offer physicians the ability to work more efficiently and are therefore uniquely positioned to play an important role in managing the increased need for surgical services as it arises in the years alread.

## FORECASTED DEMAND GROWTH IN THE NUMBER OF PROCEDURES BY SPECIALTY



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#### SERVICE OF A PLOCUL MID TO ENSURE QUARTER AND STREETS

Health care facilities in the United States are highly regulated by federal and state entities. ASCs are not excluded from this oversight.

The safety and quality of care offered in ASCs is evaluated by independent observers through three processes: state licensure, Medicare certification and voluntary accreditation.

Most states require ASCs to be licensed in order to operate. Each state determines the specific requirements ASCs must meet for licensure. Most state licensure programs require rigorous initial and ongoing inspection and reporting.

All ASCs serving Medicare beneficiaries must be certified by the Medicare program. In order to be certified, an ASC must comply with standards developed by the federal government for the specific purpose of ensuring the safety of the parient and the quality of the facility, physicians, staff, services and management of the ASC. The ASC must demonstrate compliance with these Medicare standards initially and on an ongoing basis.

In addition to state and federal inspections, many ASCs choose to go through voluntary accreditation by an independent accrediting organization. Accrediting organizations for ASCs include the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for the Accreditation of Ambulatory Surgery Facilities (AAAASF) and the American Osteopathic Association (AOA). ASCs must meet specific standards during on-site inspections by these organizations in order to be accredited. All accrediting organizations require an ASC to engage in external benchmarking, which allows the facility to compate its performance to the performance of other ASCs.

In addition to requiring certification in order to participate in the Medicare program, federal regulations also limit the scope of surgical procedures reimbursed in ASCs. Generally, services are limited to elective procedures with short anesthesia and operating times not requiring an overnight stay. These limitations do not apply to hospital outpatient departments (HOPDs).6

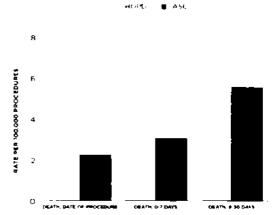
The federal government views ASCs and HOPDs as distinct types of providers. As a result, the federal regulations governing HOPDs and ASCs differ, Another reason for differing regulations is that, in a hospital, the same operating room may be used interchangeably to provide services to both inpatients and outpatients. For example, a procedure room in the HOPD may be used to perform a service for an inpatient and then used to perform the same procedure for

an ambulatory patient who is discharged home immediately thereafter. In other words, ambulatory patients seen on an outpatient basis in an HOPD may utilize exactly the same facilities used to provide services to patients who have been admitted to the hospital. Consequently, the inpatient standards for hospitals are applied to HOPDs.

On the other hand, ASCs provide services in facilities specifically designed to perform selected outpatient surgical services. The different requirements developed by the federal government appropriately reflect the fundamental differences in the hospital serting versus the ASC.\*

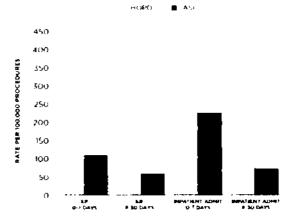
ASCs consistently perform as well as, if not better than, HOPDs when quality and safety is examined. A recent study included an examination of the rates of inpatient hospital admission and death in elderly patients following common outpatient surgical procedures in HOPDs and ASCs. Rates of inpatient hospital admission and death were lower in freestanding ASCs as compared to HOPDs. Even after controlling for factors associated with higher-risk patients, ASCs had low adverse outcome rates.

#### RATE OF ADVERSE EVENTS: DEATH



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#### RATE OF ADVERSE EVENTS: ER VISIT OR INPATIENT ADMISSION



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#### SPECIFIC FEDERAL REQUIREMENTS GOVERNING ASCS

In order to participate in the Medicate program, ASCs are required to meet certain conditions set by the federal government designed to ensure the facility is operated in a manner that ensures the safety of patients and the quality of services. Some of these requirements are highlighted in more detail below.

ASCs are required to maintain complete, comprehensive and accurate medical records. The content of these records must include a medical history and physical examination relevant to the reason for the surgery and the type of anesthesia planned. In addition, a physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and the procedure to be performed. Prior to discharge each patient must be evaluated by a physician for proper anesthesia recovery.

CMS requires ASCs to ensure patients do not acquire infections during their care at these facilities. ASCs must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting outcomes to appropriate authorities. The program must be one of active surveillance and include specific procedures for prevention, early detection, control, and investigation of infectious and communicable diseases in accordance with the recommendations of the Centers for Disease Control. In fact, ASCs have historically had very low infection rates.<sup>10</sup>

A registered nurse trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever a patient is in the ASC. To further protect patient safety, ASCs are also required to have an effective means of transferring patients to a hospital for additional care in the event an emergency occurs. Written guidelines outlining arrangements for ambulance services and transfer of medical information are mandatory. An ASC must have a written transfer agreement with a local hospital, or all physicians performing surgery in the ASC must have admitting privileges at the designated hospital. Although these safeguards are in place, hospital admissions as a result of complications following ambulatory surgery are rare.

Continuous quality improvement is an important means of assuring patients are receiving the best care possible. ASCs are required to implement and monitor policies that ensure the facility provides quality health care in a safe environment. An ASC, with the active participation of the medical staff, is required to conduct an ongoing, comprehensive assessment of the quality of care provided.

The excellent outcomes associated with ambulatory surgery reflect the commitment that the ASC industry has made to quality and safety. One of the many reasons that ASCs continue to be so successful with patients, physicians and insurers is their keen focus on ensuring the quality of the services provided.

Medicare Requirements for ASCs and Hospitals Are The Same Where Services are Comparable

Compliance with state-increasive law	M	<b>②</b>
Coverning besty	[4]	$\mathbf{M}$
Sargula: services	[]	Ø
Evaluation of quality	lacksquare	[7]
Environment	$oldsymbol{oldsymbol{oldsymbol{oldsymbol{A}}}$	র
Medical staff	[4]	<b>7</b>
Nursing services	<b>(</b>	[2]
Medical records	Ø	
Pharmaceubical services		[⊻]
Taboratory services		[4]
Radiologic services	M	✓

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A fundamental change in the way the government assures the quality of health care services is well underway. The Department of Health and Human Services has launched its Quality Initiative to assure quality health care through accountability and public disclosure.

The ASC industry is excited to have the opportunity to make its excellent outcomes more widely known to the public through this initiative. Leaders from the ASC industry, along with associations and related organizations with a focus on health care quality and safety, have come together in a collaborative effort to identify specific measures for quality appropriate to ASCs. This group, the ASC Quality Collaboration, strongly endorses the vision that measures of quality which are appropriate to ASCs should be congruent with measures utilized for other outpatient surgery settings. The continued development of these measures will involve a number of different stakeholders including ASC clinical and administrative leaders, health policy researchers, CMS and other key federal and state governmental agencies. The group will also work with the National Quality Forum to achieve consensus on the proposed quality measures.

#### **PATIENT SATISFACTION**

Patient satisfaction is a hallmark of the ASC industry. This year, more than eight million Americans will undergo surgery in an ASC. Virtually all of those patients will return home the same day and will resume most normal activities within a matter of days. Talk to these patients and you will hear how overwhelmingly satisfied they are with their ASC experience. Recent surveys show average patient satisfaction levels in ASCs exceeding 90 percent. Safe and high quality services, ease of scheduling, greater personal attention and lower costs are among the main reasons cited for the growing popularity of ASCs as a place for having surgery.

#### SUR POMDEROURS AT SIGNERAL BUT COST A CHINGS

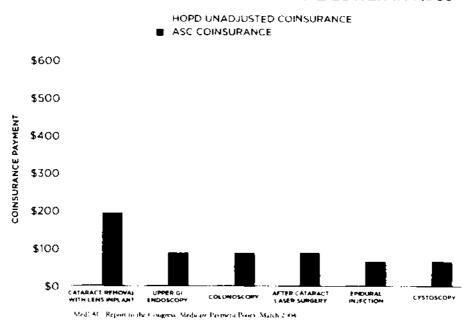
Not only are ASCs focused on ensuring patients have the best surgical experience possible, the care they provide is also more affordable. One of the reasons ASCs have been so successful is they offer valuable surgical and procedural services at a lower cost when compared to hospital charges for the same services. Beginning in 2007, Medicare payments to ASCs will be lower than or equal to Medicare payments to HOPDs for comparable services for 100 percent of procedures.

In addition, patients typically pay less coinsurance for procedures performed in the ASC than for comparable procedures in the hospital setting. For example, a Medicare beneficiary could pay as much as \$496 in coinsurance for a cataract extraction procedure performed in a HOPD, whereas that same beneficiary's copayment in the ASC would be only \$195; a Medicare beneficiary could pay as much as \$186 in coinsurance for a colonoscopy performed in a HOPD, whereas that same beneficiary's copayment for the same procedure performed in an ASC would be only

\$89. By having surgery in the ASC the patient may save as much as 61%, or more than \$300, compared to their out-of-pocket coinsurance for the same procedure in the hospital.

Without the emergence of ASCs as an option for care, health care expenditures would have been billions of dollars higher over the past three decades. Studies have shown the Medicare program would pay approximately \$464 million more per year if all procedures performed in an ASC were instead furnished at a hospital. Private insurance companies tend to save similarly, which means employers also incur lower health care costs by utilizing ASC services. Employers and insurers, particularly managed care entities, are driving ASC growth in many areas, because they recognize ASCs are able to deliver consistent, high quality outcomes at a significant savings. As the number of surgical procedures performed in ASCs grows, the Medicare program may realize even greater savings - and of course Medicare beneficiaries will realize additional out-of-pocket savings as well. 14

#### MEDICARE COINSURANCE RATES ARE LOWER IN ASCS



#### THE ASC INDUSTRY SUPPORTS DISCLOSURE OF PRICING INFORMATION

It is the general practice of ASCs to make pricing information available to the patient in advance of surgery. The industry is eager to make price transparency a reality, not only for Medicare beneficiaries, but for all patients. To offer maximum benefit to the consumer, these disclosures

should outline the total price of the planned surgical procedure and the specific portion for which the patient would be responsible. This will empower health care consumers as they evaluate and compare costs for the same service amongst various health care providers.

### ASCS IMPROVE PATIENT CHOICE, DEMAND FOR ASCS GROWS

Technological advancement has allowed a growing range of procedures to be performed safely on an outpatient basis. Faster acting and more effective anesthetics and less invasive techniques, such as arthroscopy, have driven this outpatient migration. Procedures that only a few years ago required major incisions, long-acting anesthetics and extended convalescence can now be performed through closed techniques utilizing short-acting anesthetics, and with minimal recovery time. As medical innovation continues to advance, more and more procedures will be able to be performed safely in the outpatient setting.

The number of ASCs continues to grow in response to demand from the key participants in surgical care—patients, physicians and insurers. This demand has been made possible by technology, but has been driven by high levels of patient satisfaction, efficient physician practice, high levels of quality and the cost savings that have benefited all. The number of Medicare certified ASCs has grown from 2786 in 1999 to 4506 in 2005, with an average annual growth rate of 8.3%.<sup>14</sup>

Further impetus to future ASC growth has been given by MedPAC, which has recommended that the CMS list of approved ASC procedures be expanded. This would

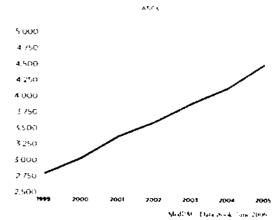
# ASCS WILL CONTINUE TO LEAD INNOVATION IN OUTPATIENT SURGICAL CARE

As leaders of the revolution in surgical care who led to the establishment of affordable and safe outpatient surgery, the ASC industry has shown itself to be ahead of the curve in identifying promising avenues for improving the delivery of health care.

With a solid track record of performance in stakeholder satisfaction, safety, quality and cost management, the ASC industry is already embracing the changes that will allow it to continue to play a leading role in raising the standards of performance in the delivery of outpatient surgical services.

As always, the ASC industry welcomes any opportunity to clarify the services it offers, the regulations and standards governing its operations, and the ways in which it ensures safe, high-quality care for patients.

#### NUMBER OF MEDICARE-CERTIFIED ASCS



allow a broader range of choice for patients and surgeons. Specifically, MedPAC has recommended the procedures approved for the ASC setting he revised so that ASCs can receive payment for any surgical procedure, with the exception of those surgeries requiring an overnight stay or which pose a significant safety risk when furnished in an ASC.8 Adoption of these recommendations would allow Medicare beneficiaries to access an extended range of surgical services—a range of surgical services which is already available to patients with private insurance.<sup>15</sup>

#### POLICY CONSIDERATIONS

Given the continued fiscal challenges posed by administering health care programs, policy makers and regulators should continue to focus on fostering innovative methods of health care delivery that offer safe, high-quality care so progressive changes in the nation's health care system can be implemented.

Support should be reserved for those policies that promote the utilization of sites of service providing more affordable care while maintaining high quality and safety standards. In light of the many benefits ASCs have brought to the nation's health care system, it will be important for future payment and coverage policies to continue to strengthen access to and utilization of ASCs.



#### **ENDNOTES**

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- 12 Deficit Reduction Act of 2005.
- 13 MedPAC, Report to the Congress: Medicare Payment Policy, March 2004.
- 14 MedPAC, Data Book, June 2006.
- 15 Thomson Medstat, MarketScan@ Outpatient Claims Data, 2005.

#### This report was prepared by the ASC Coalition and is further supported by the following organizations:

Alabama Ambulatory Surgery Association

American Association of Ambulatory Surgery Centers

AmSurg

Arizona Ambulatory Surgery Center Association

Arkansas Ambulatory Surgery Association

California Ambulatory Surgery Association

Colorado Ambulatory Surgery Center Association

FASA

Florida Society of Ambulatory Surgical Centers

Foundation for Ambulatory Surgery in America

Freestanding Ambulatory Surgery Center Association of Tennessee

Georgia Society of Ambulatory Surgery Centers

Healthmark Industries Co

**HealthSouth** 

Idaho Ambulatory Surgery Center Association

Illinois Freestanding Surgery Center Association

Indiana Federation of Ambulatory Surgical Centers

Iowa Association of Ambulatory Surgery Centers

Kansas Association of Ambulatory Surgery Centers

Kentucky Ambulatory Surgery Center Association

Louisiana Ambulatory Surgery Association

Maine Ambulatory Surgery Center Coalition

Maryland Ambulatory Surgical Association

Massachusettes Association of Ambulatory Surgery Centers

Mississippi Ambulatory Surgery Association

Missouri Ambulatory Surgery Center Association

National Surgical Care

Nevada Ambulatory Surgery Association

New Hampshire Ambulatory Surgery Center

NovaMed

Nueterra Healthcare

Ohio Association of Ambulatory Surgery Centers

Pennsylvania Ambulatory Surgery Association

South Carolina Ambulatory Surgery Center Association

South Dakota Association of Specialty Care Providers

Symbion Healthcare

Texas Ambulatory Surgery Center Society

United Surgical Partners International

Utah Ambulatory Surgery Center Association

Washington Ambulatory Surgery Center Association

Wisconsin Surgery Center Association

For additional information please contact:

AAASC: Craig Jeffries, craigjeffries@aaasc.org

FASA: Sarah Silberstein, ssilberstein@fasa.org

## **Attachment 4**

# OR Work Group Public Hearing Presentation Raleigh Orthopaedic Clinic

Good morning. My name is Karl Stein and I am the administrator for Raleigh Orthopaedic Clinic. During my healthcare career I previously served as an administrator at a community hospital in Indiana.

Raleigh Orthopaedic Clinic is comprised of nineteen physicians and is the largest orthopedic practice in Wake County. Our physicians have privileges at Rex Hospital and WakeMed's New Bern and North locations. The group has four office locations and serves patients from all of Wake County and a large region of eastern North Carolina. In 2005, ROC physicians performed a total of 6.700 surgical procedures; ambulatory surgery procedures comprised 72 percent of the total. ROC physicians helped found and are active participants in the Wake County Medical Society's Project Access, which provides free office visits for low income patients.

Raleigh Orthopaedic Clinic has submitted multiple petitions to change the operating room methodology. We have petitioned for an adjusted need determination for ambulatory ORs in Wake County. Also, we jointly petitioned with other groups that proposed additional OR need determinations in each of the health service areas across the state. Even though our petitions have been denied, I am optimistic about the willingness of the OR Work Group to listen to our concerns and make needed changes.

My comments to you are encompassed by three main points:

- 1) Make changes that promote faimess.
- 2) Fix the methodology so that OR capacity is routinely added to keep pace with the growth in surgery demand.
- Operational issues related to patient access, charity care, accreditation, staffing levels and quality should be addressed through the Certificate of Need review / conditional approval process.

When I talk about fairness, I ask you to make the OR methodology fair to all concerned. You should judge the current OR policies and methodology from the perspective of the average surgeon or the administrator of an average sized community hospital. Ask them what they think about the manipulations of the OR policies and CON process that resulted in the conversion of endoscopy rooms to operating rooms. You know that when loopholes like that are exploited, it undermines the entire process. Please consider making changes to the language in the OR Chapter to include statements such as:

"Additions to the operating room inventory must be consistent with and not exceed the OR need determinations in the SMFP. C-section operating rooms, dedicated open heart rooms, trauma operating rooms, other special operating rooms, endoscopy procedure rooms or other procedure rooms (that have been excluded from the OR adjusted planning inventory in the SMFP) can not be converted and / relocated to become surgical operating rooms unless CON approval has first been obtained in response to SMFP-published OR need determinations that are open to all CON applicants."

Fairness also relates to the equitable distribution of surgical operating rooms. In at least one of our previous petitions we discussed the fact that there is a huge disparity in the number of operating rooms per capita from one county to another. Surprisingly, Wake County has substantially fewer surgical operating rooms as compared to the other large metropolitan counties like Mecklenburg, Durham, Forsyth and Guilford.

Look at the availability of operating rooms in rural counties. The OR methodology has no mechanism to improve geographic access. With the present methodology it is most unlikely that a new ambulatory surgery center could ever be developed in a small rural county.

You really need to look at the OR methodology to see if it works to decrease the disparity over time. My sense is that the current OR methodology is really broken -- it has allowed a

few hospital systems across the state to become exceedingly dominant in their markets while the smaller hospitals and physician groups are totally shut out. Please fix the methodology to give the surgeons and the community hospitals a level playing field to compete for CON approval.

Keeping pace with demand is my second point. Look at the actual growth rates in surgery volumes across the state in the handout and the chart. Over the past three years, inpatient surgery has shown no growth. In contrast, ambulatory surgery has increased steadily. I expect that in future years the inpatient surgery growth will increase somewhat due to the growth and aging of the population and ambulatory surgery cases will certainly continue to increase. How many people here think that the statewide growth of at least 2.5 percent in total surgery cases is too optimistic?

Based on the statewide surgery data, I strongly encourage you to modify the methodology so that it will generate at least 2.5 percent additional OR capacity each year. This translates to approximately 30+ additional operating rooms each year. This can be accomplished by changing the assumption of the annual hours per operating room from the current 1872 annual hours down to 1632 annual hours.

Now, there are three components that support justification for the 1632 annual hours assumption:

The majority of operating rooms across the state are staffed only one shift per day for 8 hours.

255 days per year is the number of actual workdays that surgery cases can be scheduled, which is 260 annual weekdays minus an average of 5 weekday holidays per year.

80 percent availability relates to maintenance, cleaning and staffing factors that preclude an operating room from being fully scheduled.

These three factors multiplied together yield 1632 annual hours.

What will happen if we don't fix the OR methodology is that tensions between hospitals and surgeons will increase and patient care will suffer. Raleigh Orthopaedic Clinic surgeons already have real difficulty scheduling surgery cases at the existing surgery facilities in Wake County. We have plans to recruit additional surgeons but we have no assurances that they will be able to gain access to the few existing ORs that are appropriate for their orthopedic specialties. If OR capacity does not increase to keep pace with demand, then we should stop spending money on recruitment.

The current methodology shows no need for additional operating rooms anywhere in the state through 2009. I think that having another planning year that puts no operating rooms in the pipeline for development would be a serious mistake. Also consider that a methodology that is <u>overly frugal</u> in terms of the number of OR need determinations will raise the stakes in competitive CON reviews and will guarantee lengthy and costly litigation.

My last point relates to operational issues including accreditation, staffing levels, quality, patient access and charity care. All of these issues should be addressed through the Certificate of Need regulations, competitive review and conditional approval process. The CON Section routinely attaches conditions to their CON approvals to ensure that the project will be developed in material compliance with the representations in the application. In addition, the CON law already provides the mechanisms for the Department to take enforcement action in Wake County Superior Court. With these regulatory provisions already in place, the OR methodology has no need to pre-qualifying potential CON applicants.

Please also know that the Raleigh Orthopaedic Clinic physicians willingly provide charity care to hospital inpatients and patients in our offices. If we ever have an opportunity to pursue CON approval for operating rooms, we would certainly commit to provide both access for all patient payor categories and a substantial level of charity care.

Thank you for your attention.

## Attachment 5

<del></del>			•
<del>-</del>		-	
Wake County Operating Room Data and Inventory	Inpatient		Combined
Information - 2008 Plan with WakeMed Dedicated Open Heart	Cases minus C	Ambulatory	Inpatient plus
Rooms and Cases Excluded	Section	Cases	Ambulatory
Wake County Operating Room Volumes (Proposed 2008 Plan)	21029	55789	76818
Subtract 4 Dedicated ORs and Open Heart Cases	-931	0	0
Revised Statistics	20098	55789	75887
Hours per case (same assumption as OR methodology)	3.0	1.5	
Total Estimated Hours	60294.0	83683.5	143977.5
Population Growth Factor 2006-2010 (same assumption as OR m	ethodology)	_	0.1479
Total Surgical Hours Anticipated in 2010			165,272
ROC Recommended Hours per Room	Ī		
9 hrs per day / 260 days per year / 80%			1872
Projected Number of ORs Needed			88.3
Adjusted Planning Inventory for Wake ORs (same as OR methodo	ology)	_	90.0
Subtract 4 Open Heart ORs			-4.0
			86.0
Projected Need for Additional ORs in 2010 (excluding 4 Open Hea	art ORs)		2.3

## Attachment 6



# Centers for Medicare & Medicaid Services

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Details for: CMS REVISES PAYMENT STRUCTURE FOR AMBULATORY SURGICAL CENTERS AND PROPOSES POLICY AND PAYMENT CHANGES FOR HOSPITAL OUTPATIENT

Return to List

For Immediate

Release:

Monday, July 16, 2007

Contact:

CMS Office of Public Affairs

202-690-6145

# CMS REVISES PAYMENT STRUCTURE FOR AMBULATORY SURGICAL CENTERS AND PROPOSES POLICY AND PAYMENT CHANGES FOR HOSPITAL OUTPATIENT

NEW STEPS TO ENCOURAGE HOSPITAL EFFICIENCIES AND QUALITY

The Centers for Medicare & Medicaid Services (CMS) today issued a final rule revising the payment system for services furnished to people with Medicare in ambulatory surgical centers (ASCs) to better align payments for similar services furnished in a hospital outpatient department (HOPD) or a physician's office. CMS also issued a proposed rule that would update Medicare payment for services in HOPDs under the Outpatient Prospective Payment System (OPPS) and would set new payment rates for ASCs under the revised system effective for services in calendar year (CY) 2008.

The ASC final rule expands beneficiary access to surgical procedures in ASCs and implements steps to make ASC payments more accurate, while aligning payments across Medicare's payment systems to encourage efficient and appropriate choices of outpatient settings for ambulatory surgical procedures. CMS expects to make payments of almost \$3 billion in CY 2008 to the approximately 4,600 ASCs that participate in Medicare.

"The system we are announcing today will promote the goals of quality and efficiency in care furnished to people with Medicare in ambulatory surgical centers," said CMS Acting Administrator, Leslie V. Norwalk, Esq. "In addition, this revised system will take a major step toward eliminating financial incentives for choosing one care setting over another, thus assuring that patients' needs come first."

The proposed OPPS/ASC rule, published concurrently with the ASC final rule, would implement new steps to encourage more efficient care in hospital outpatient departments by providing hospitals with greater flexibility to manage their resources. The proposal also would ensure appropriate payment for high quality hospital outpatient services under the hospital Outpatient Prospective Payment System (OPPS). The reforms included in this proposed rule are intended to encourage quality and constrain rapid and accelerating growth in Medicare volume and expenditures for hospital outpatient services.

"As the number of services provided in hospital outpatient setting continues to increase annually," said Ms. Norwalk, "we are committed to working with hospitals to ensure the care provided to beneficiaries is appropriate, cost-effective and high quality. Today's proposed rule includes proposed hospital quality measures specific to hospital outpatient care, following the quality measures that have been successfully implemented in the hospital inpatient setting. In addition, this rule's proposal to increase the size of the OPPS payment bundles will give hospitals the flexibility to manage their resources in the most efficient way possible."

#### Revised Payment Methodology For ASCs

The final rule allows ASCs to be paid for any surgical procedure that CMS determines does not pose a significant safety risk to Medicare beneficiaries when performed in an ASC and that is not expected to require an overnight stay. As a result, the final rule adds about 790 procedures for ASC payment beginning in CY 2008. The proposed OPPS/ASC rule would add several additional procedures, which would result in approximately 3,300 covered surgical procedures under the revised ASC payment system. CMS expects that as a result of the significant expansion of surgical procedures paid in ASCs, beneficiaries will experience greater access to surgical services in appropriate settings.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to revise the ASC payment system no later than January 1, 2008. Consistent with the recommendations of the November 2006 Government Accountability Office Report (GAO Report) on ASC costs and payment, CMS is implementing the revised ASC payment system using hospital OPPS relative payment weights as a guide.

The revised ASC payment rates are based on the ambulatory payment classifications (APCs) used to group procedures under the OPPS. As required by the MMA, the revised ASC payment system is budget neutral; that is, it is estimated to have no net effect on Medicare expenditures in CY 2008 compared to the level of expenditures that would have occurred in the absence of the revised payment system. Consistent with the GAO Report, which found that procedures performed in ASCs are generally less costly than those performed in the HOPD, the proposed ASC payment rates for CY 2008 are estimated to be set at 65 percent of the OPPS rates for the corresponding procedures.

Many of the surgical procedures that are included as covered surgical procedures eligible for payment in ASCs under the revised system are procedures that have been performed predominantly in physicians' offices. To avoid creating payment incentives to perform those services in ASCs when they could be safely performed at less cost to Medicare and the beneficiary in a physician's office, payment for surgical procedures identified as 'office-based' is capped at the nonfacility practice expense component of Medicare's Physician Fee Schedule (MPFS) payment rate in the physician office setting. A separate payment to the physician performing these surgical procedures would be made for their professional services provided in the ASC facility.

Under the revised system, Medicare will make separate payment for covered ancillary services, such as radiology services and some drugs and biologicals that are provided integral to covered surgical procedures. Medicare will also provide separate payment to ASCs for the brachytherapy sources that are implanted through surgically placed needles in the treatment of prostate cancer. In addition, Medicare will make payment adjustments for those ASC procedures with high device costs which ensure that the ASC payment includes the same payment for an implantable device as when the procedure is performed in a hospital outpatient department. Procedures with high device costs are those in the OPPS for which the cost of the device equals or exceeds 50 percent of the median cost of the APC.

The ASC payment system will be updated annually through proposed and final rulemaking in close association with updates to the OPPS and the MPFS. The ASC payment rates in the CY 2008 OPPS/ASC proposed rule are based upon the policies of final ASC rule, updated to comport with the proposed OPPS APC recalibration and proposed OPPS payment policies for CY 2008.

The final CY 2008 ASC payment rates will be published in the OPPS/ASC final rule in November 2007, some of which will be incrementally phased in over a four year transition period, with their full implementation in CY 2011. In addition, CMS will account for geographic wage variation in individual ASC payments by applying the wage index to 50 percent of the ASC payment.

#### Proposed 2008 Policy And Payment Changes For HOPDs And ASCs

Prior to the implementation of the OPPS, beneficiary coinsurance for hospital outpatient services often resulted in beneficiary responsibility for more than half of the actual payment for the HOPD services. In the CY 2008 proposed rule, beneficiary liability under the OPPS would continue to be reduced under a formula that is designed to provide a gradual transition to 20 percent coinsurance. Based on the proposed rule, the aggregate beneficiary liability is estimated to be 26 percent of the total payment, and almost 3100 services (or 23 percent of all types of services billed under the OPPS) would meet the target coinsurance of 20 percent, increased from about 2600 (or 19 percent of all types of services) in CY 2007.

The proposed rule includes a 3.3 percent inflation update in Medicare payment rates for services paid under the OPPS for CY 2008. CMS projects that hospitals would receive \$34.9 billion in CY 2008 for outpatient services furnished to Medicare beneficiaries under the proposed rule. The proposed changes would affect outpatient services furnished by general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children's hospitals, and cancer hospitals.

These statutory payment increases are projected to continue a trend of rapid growth in hospital outpatient expenditures. CMS projects that the expenditures under the OPPS in CY 2008 will be approximately 10.5 percent higher than the estimated CY 2007 expenditures. The current rate of growth in expenditures is of great concern to CMS because of its impact not only on taxpayers, but also on beneficiaries whose monthly premiums must pay for 25 percent of Part 8 expenditures.

While payments to hospitals under the OPPS have increased over the years, these payment increases have not been specifically tied to quality improvements. The statute now requires that the annual payment update factor in CY 2009 and subsequent years be reduced by 2.0 percentage points for hospitals that do not report quality measures. This proposed rule proposes 10 hospital outpatient quality measures for purposes of the quality reporting requirement.

The proposed quality measures include five emergency department acute myocardial infarction transfer measures, two surgical care improvement measures, and one measure each for the treatment of heart failure, community-acquired pneumonia, and diabetes. CMS is also seeking public comment on 30 additional measures that are under consideration for reporting in future years.

CMS is also proposing to increase the size of the OPPS payment bundles as recommended by the Medicare Payment Advisory Commission (MedPAC). This proposal would provide greater flexibility to hospitals in implementing efficient care. Currently, certain items and services, including low cost drugs, anesthesia services, operating and recovery room use, implantable devices, and medical supplies are packaged in the payment for the associated APCs. CMS is proposing to package payment for seven additional categories of supportive and ancillary services in order to encourage hospital efficiencies in selecting the most clinically appropriate diagnostic and treatment approaches.

In addition, CMS is proposing to establish a new type of APC, called a composite APC, through which a single payment would be made for multiple major procedures performed in a single hospital encounter. CMS is proposing to establish two composite APCs for 2008, one for low dose rate prostate brachytherapy and one for cardiac electrophysiological evaluation and ablation. These composite APCs allow CMS to use the most complete data for rate setting when procedures are commonly provided in combination with one another.

# Attachment 7

North Carolina Department of Health and Human Services

Division of Facility Services

Acute and Home Care Licensure and Certification Section 1205 Umstead Drive, 2712 Mail Service Center

Raleigh, North Carolina 27699-2712

Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only

License # H0065 Computer: 953429 PC \_\_\_\_\_\_ Medicare # 340114

Date \_1-3-87

License Fee:

\$7,175.00

## 2007 **HOSPITAL LICENSE** RENEWAL APPLICATION

Legal Identity of Applicant (Full legal name of corpora		legal entity owning the enterprise or service.)
Doing Business As (d/b/a) name(s) under whicl	the facility or services are advertise	d or presented to the public:
PRIMARY: Rex Hos Other: Rex Hea Other: Rex Reh		
Facility Mailing Address:	4420 Lake Boone Trail Raleigh, NC 27607	
Facility Site Address:  County: Telephone: Fax:	4420 Lake Boone Trail Raleigh, NC 27607 Wake (919)784-3100 (919)784-3336	
Administrator/Director: Title: <u>President</u> (Designated agent (individual) r	David Strong esponsible to the governing body (owner) for	r the management of the licensed facility)
Chief Executive Officer: _ (Designated agent (individual) re	Gary L. Park esponsible to the governing body (owner) for	Title: CEO the management of the licensed facility)
Name: Maraus	act for any questions regarding this for Milson	Orm: Telephone: (919) 784 - 6394
		Date 12 29 100 Amouni \$ 7,175.00 al original Modifies, or disability in completent or the provision of the state of the provision of the state of the provision of the state o

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

## 7. Specialized Cardiac Services (for questions, call 855-3865 [Medical Facilities Planning])

(a) Cardiac Catheterization	Interventional Cardiac Cardiac Catheterization ICD-9 36.01, 36.02, 36.05 37.21, 37.22, 37.23, 37.25 35.52, 35.71, 35.96		Electro-physiology 37.26, 37.27, 37.34, 37.70, 37.71, 37.72, 37.73, 37.74, 37.75, 37.76, 37.77, 37.79, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 37.89, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, 00.50, 00.51, 00.52, 00.53, 00.54
1. Number of Units of Equipment		3	t .
2. Total Annual Number of Cases*	2,086	1,102	458
3. Of Total in #2, Number of Patients Age 14 & under	0	O	0
Of Total in #2, Number of Cases     Performed in Mobile Unit**	0	0	0

\* One case is defined to be one visit or trip by a patient to an operating room or catheterization laboratory for a single or multiple procedures or catheterizations. Count each visit once regardless of the number of diagnostic, interventional, and/or EP procedures performed within that visit.

**	Please report name of mobile vendor:
	Number of operating hours per week on site:

(b) Open Heart Surgery (utilizing heart/lung bypass machines)	
Number of Dedicated Open Heart Surgery     Operating Rooms	0
2. Number of Heart-Lung Bypass Machines	3
3. Total Annual Number of Procedures	359
4. Of total in #3, Number of Procedures on Patients Age 14 & under	0

License No: H0065

Facility ID: 953429

Rex Hospital

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

# 8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

Surgical Operating Rooms and Cases

[1] Please report Surgical Operating Rooms built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals and COPY this sheet and Submit a duplicate of this page for each campus.

(Campus - If multiple sites: Rex Hospital - Main Campus Raleigh,

Type of Room	Number of Rooms	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases	Ambulatory Cases
[A]	[B]	[C]	[D]	[E]
Dedicated Open Heart Surgery (from 7b)			0	
Dedicated C-Section	0	0	0	
Other Dedicated Inpatient Surgery	0	0		
Dedicated Ambulatory Surgery	0		Ų	
Shared - Inpatient / Ambulatory Surgery	77	Ö	9,255	15,323
Total of Surgical Operating Rooms & Cases (Columns [D] & [E] should equal Totals in 8(d))	77	0	9,255	15,323

[2] Does this facility have additional surgical operating rooms (i.e., not listed above) that are	e being developed	pursuant to a
	YesX	
If "Yes," please list the Types of Rooms and Number of Rooms being developed:		

b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of Gastrointestinal Endoscopy Rooms and the number of cases performed in these rooms during the reporting period. (NOTE: Other procedure rooms should be included in Section 9 on Page 10 of this application.) Count each patient as one case regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room	Number Of Rooms	Of the Rooms in Column [B], the number "Not in Use"	Inpatient Cases	Ambulatory Cases	Total Number of Procedures
[A]	(B)	{(C]_	<b>[D)</b>	(E)	( <b>F</b> )
Gastrointestinal Endoscopy Rooms & Cases	4	0	GI: 992	GI: 5,795	G1: 8,012
			Non GI: 88	Non GI: 122	

[2] Does this facility have <u>additional Gastrointestinal Endoscopy Rooms</u> (i.e., <u>not</u> listed <u>developed</u> pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714?	 
If "Yes." please list the Number of Rooms being developed:	 

License No: H0065

Facility ID: 953429

Rex Hospital

License No: H0065 Facility ID: **953429** 

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

### 8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

#### a) Surgical Operating Rooms and Cases

[1] Please report Surgical Operating Rooms built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals and COPY this sheet and Submit a duplicate of this page for each campus.

(Campus - If multiple sites: Kex Healthcare of Cary

Type of Room	Number of Rooms	Of the Rooms in Column [B], the number "Not in Use"	Inpatient Cases	Ambulatory Cases
[A]	{B}	[C]	[D]	[E]
Dedicated Open Heart Surgery (from 7b)	0	0	0	
Dedicated C-Section	0	٥	0	
Other Dedicated Inpatient Surgery	0	0	0	
Dedicated Ambulatory Surgery	4	0	- ¥	2,899
Shared - Inpatient / Ambulatory Surgery	Ó	0		0
Total of Surgical Operating Rooms & Cases (Columns [D] & [E] should equal Totals in 8(d))	4	0	0	2,849

[2] Does this facility have additional surgical operating rooms (i.e., not listed above) that ar	re being develor	ped pursuant to a
Certificate of Need or pursuant to the exemption provided in Senate Bill 714?	Yes _	<u>X</u> No
If "Yes," please list the Types of Rooms and Number of Rooms being developed:		

#### b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of Gastrointestinal Endoscopy Rooms and the number of cases performed in these rooms during the reporting period. (NOTE: Other procedure rooms should be included in Section 9 on Page 10 of this application.) Count each patient as one case regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room	Number Of Rooms	Of the Rooms in Column (B), the number "Not in Use"	Inpatient Cases	Ambulatory Cases	Total Number of Procedures	
[A]	[B}	[C]	[D]	(E)		
Gastrointestinal Endoscopy Rooms & Cases			G1: O	G1: o	GI:	
	0	0	Non Gl: O	Non G1:	Non CI:	

[2] Does this facility have <u>addideveloped</u> pursuant to a Certific Senate Bill 714?	tional Gastrointesti cate of Need or purs	nal Endoscopy F want to the exem	Rooms (i.e., <u>not</u> aption provided	listed above) <u>th</u> in Yes	
If "Yes," please list the Numbe	r of Rooms being d	eveloped:			
Revised 08/2006		<del></del>		<b>37</b>	Page 8

# 8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases continued

#### c) Average Room Availability and Average Case Times:

Type of Room	"Resource Hours" * (Average <u>Hours</u> per Room per Day Routinely Scheduled for Use)	Average "Case Time" ** in Minutes for Inpatient Cases	Average "Case Time" ** in <u>Minutes</u> for Ambulatory Cases
Surgical Operating Rooms	967	160	108
Gastrointestinal Endoscopy Rooms	7.75	52	44

<sup>\* &</sup>quot;Resource Hours" = Average number of hours per Room per Day routinely scheduled to be available for performance of procedures. (Example: 2 rooms @ 8 hours per day <u>plus</u> 2 rooms @ 10 hours per day <u>equals</u> 36 hours per day; <u>divided</u> by 4 rooms <u>equals</u> an average of 9 hours / per room / per day.)

d) Surgical Specialty - Of the cases in Surgical Operating Rooms (Item 8.a.[1]), enter the number of cases by surgical specialty area in the chart below:

Specialty Area	Inpatient Cases	Ambulatory Cases
Cesarean Sections	2,068	
Cystoscopy	3	27
Endoscopy (all endo types performed in Surgical Operating Room)	3	8
General	1,955	3,740
Gynecology	947	
Neurosurgery	147	
Open Heart	359	
Ophthalmology	6	670
Oral Surgery	t	13
Orthopedics	2,352	5,589
Otolaryngology	62	3,108
Plastic Surgery	351	2,366
Podiatry	1	401
Thoracic (other than open heart)	31	4
Urology	42-7	804
Other (Specify)	536	412
Total Surgical Operating Room Cases (Totals should equal totals 8.a[1], columns D & E)	9,255	18,000

License No: H0065

Facility ID: 953429

<sup>\*\* &</sup>quot;Case Time" = Time from Room Set-up Start to Room Clean-up Finish. Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. <u>NOTE</u>: This definition includes all of the time for which a given procedure requires an ONPR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure. For purposes of scheduling and efficiency analysis, this definition is ideal because it includes all of the time that an OR/PR must be reserved for a given procedure.

License No. H0065

### 9. Non-Gastrointestinal Procedure Rooms and Cases

Please report only rooms or cases not reported in 8a or 8b: Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of procedures other than gastrointestinal endoscopy. (Do not list a room for more than one use). Please note: Any procedures performed in these rooms should not be hilled as having occurred in an operating room or reported in 8 as procedures performed in an operating room. Cases: Count each patient as one case regardless of the number of procedures performed while patient was in the room.

Use	Number of Rooms	Inpatient Cases	Ambulatory Cases
Cast Procedures	0	o	o
Cystoscopy	1	170	461
Endoscopies (other than GI Endoscopies) unless they were performed in a surgical operating room	0	0	0
Lithotripsy		9	399
Special Procedures/Angiography (neuro & vascular but not including cardiac eath.)	3	1,301	d, 60 1 44
Sutures	0	0	Ó
YAG Laser	U	4	3
Other (Specify) Minner Procedures**	4	66	4,397
Totals	9	1,550	7,874

I Lithotripsy is provided by a mobile service from October 1, 2005 to July 9, 2006 lithotripsy services were available 8 days per month. With the addition of a Second mobile service that increased to 12 days per month beginning July 10, 2006

Revised 08/2006

As of October 17,2005, her odded 4 moor procedure rooms, closed one moor procedure room and the YAG laser room, for a new total of a procedure rooms

North Carolina Department of Health and Human Services Division of Facility Services Acute and Home Care Licensure and Certification Section

1205 Umstead Drive, 2712 Mail Service Center

Raleigh, North Carolina 27699-2712

Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only

License # H0199 Computer: 943528 PC \_\_\_\_\_\_\_\_ Medicare # 340069

Date 12 19/0

License Fee:

\$8,275.00

## 2007 HOSPITAL LICENSE RENEWAL APPLICATION

Legal Identity of Applicant: (Full legal name of corporat	: WakeMed tion, partnership, individual, or other legal entity owning the enterprise or service.)
Doing Business As (d/b/a) name(s) under which	n the facility or services are advertised or presented to the public:
PRIMARY: WakeMac Other: Other:	<u>ed</u>
Facility Mailing Address:	P O Box 14465 Raleigh, NC 27620-4465
Facility Site Address:  County: Telephone: Fax:	3000 New Bern Ave Raleigh, NC 27610 Wake (919)350-8000 (919)350-8868
Administrator/Director: Title: <u>President and CEO</u> (Designated agent (individual) re	William K Atkinson, Ph.D. esponsible to the governing body (owner) for the management of the licensed facility)
Chief Executive Officer: (Designated agent (individual) re	William K Atkinson, Ph.D. Title: President and CEO sponsible to the governing body (owner) for the management of the licensed facility)
Name of the person to contr	act for any questions regarding this form:
Name: W. Stan Taylor,	Vice President, Corporate Planning and Managed Care Telephone: 919-350-8108
E-Mail: staylor@wakem	ed.org
	<b>⊘</b> 7 3 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5
	12 8 06
	8,275.00
	J453XV5
"The N.C. Department of Health and Human So	crysces does not discriminate on the basis of race, color, national origin, and not, ego, or disability in employment or the provision of services

License No: <u>H0199</u> Facility ID: <u>943528</u>

# 7. Specialized Cardiac Services (for questions, call 855-3865 [Medical Facilities Planning])

(a) Cardiac Catheterization	Diagnostic Cardiac Catheterization ICD-9 37.21, 37.22, 37.23, 37.25	Interventional Cardiac Catheterization- ICD-9 36.01, 36.02, 36.05, 36.06, 36.07, 36.09; 35.52, 35.71, 35.96	Electro-physiology 37.26, 37.27, 37.34, 37.70, 37.71, 37.72, 37.73, 37.74, 37.75, 37.76, 37.77, 37.79, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 37.89, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, 00.50, 00.51, 00.52, 00.53, 00.54
1. Number of Units of Equipment		8	2
2. Total Annual Number of Cases*	5,536 (8,302)***	3,521 (3,521)***	1,120 (1,417)***
3. Of Total in #2, Number of Patients Age 14 & under	0	0	0
4. Of Total in #2, Number of Cases Performed in Mobile Unit**	0	0	0

\*\*\*Procedures done in each category

\* One case is defined to be one visit or trip by a patient to an operating room or catheterization laboratory for a single or multiple procedures or catheterizations. Count each visit once regardless of the number of diagnostic, interventional, and/or EP procedures performed within that visit,

**	Please report name of mobile vendor: <u>not applicable</u>
	Number of operating hours per week on site: <u>not applicable</u>

(b) Open Heart Surgery (utilizing heart/lung bypass machines)	
Number of Dedicated Open Heart Surgery     Operating Rooms	4
2. Number of Heart-Lung Bypass Machines	6
3. Total Annual Number of Procedures	931
4. Of total in #3, Number of Procedures on Patients Age 14 & under	0



#### 8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

#### a) Surgical Operating Rooms and Cases

[1] Please report <u>Surgical Operating Rooms</u> built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals and COPY this sheet and Submit a duplicate of this page for each campus.

(Campus - If multiple sites: WakeMed Raleigh ALL SITES)

Type of Room	Number of Rooms	Of the Rooms in Column [B], the number "Not in Use"	Inpatient Cases	Ambulatory Cases
[A]	{B]	[C]	[D]	(E)
Dedicated Open Heart Surgery (from 7b)	4	0	981	
Dedicated C-Section	3	0	1,194	
Other Dedicated Inpatient Surgery	0	0	0	
Dedicated Ambulatory Surgery	4	0		3,519
Shared - Inpatient / Ambulatory Surgery	18	0	6,960	10,110
Total of Surgical Operating Rooms & Cascs (Columns [D] & [E] should equal Totals in 8(d))	29	0	9,135	13,629

[2] Does this facility have <u>additional surgical operating rooms</u> (i.e., <u>not</u> listed above) that a Certificate of Need or pursuant to the exemption provided in Senate Bill 714?	ed pursuant to a No
If "Yes," please list the Types of Rooms and Number of Rooms being developed:	 

#### b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of <u>Gastrointestinal Endoscopy Rooms</u> and the number of cases performed in these rooms during the reporting period. (<u>NOTE</u>: <u>Other procedure rooms</u> should be included in Section 9 on Page 10 of this application.) Count <u>each patient as one case</u> regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room	Number Of Rooms	Of the Rooms in Column (B), the number "Not in Use"	Inpatient Cases	Ambulatory Cases	Total Number of Procedures
[A]	[B]	[C]	<b>(D</b> )	[E]	[F]
Gastrointestinal Endoscopy Rooms & Cases	6	0	GI: 2,642	GI: 4,376	7,018
			Non GI:	Noa GI:	Non GI:

[2] Does this facility have <u>additional Gastrointestinal Endoscopy Rooms</u> (i.e., <u>not</u> listed eyeloped pursuant to a Certificate of Need or pursuant to the exemption provided in	ed ab	ove) tha	t are being
Senate Bill 714?	_	Yes	<u>X</u> No
If "Yes," please list the Number of Rooms being developed:			

Revised 08/2006

License No: H0199

Facility ID: 943528

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

#### Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases continued

c) Average Room Availability and Average Case Times:

WAKEMED RALEIGH ALL SITES

License No: H0199

Facility ID: 943528

Type of Room	"Resource Hours" *  (Average <u>Hours</u> per  Room per Day  Routinely Scheduled  for Use)	Average "Case Time" ** in Minutes for Inpatient Cases	Average "Case Timc" ** in <u>Minutes</u> for Ambulatory Cases
_	7.4/hours/room/day/	178 Main OR	120 Main OR
Surgical Operating Rooms	365 days per year	372 Open Heart	69 Open Heart
Gastrointestinal Endoscopy Rooms	5.7/hours/room/day/	44	54
	365 days per year	44	J4

<sup>\* &</sup>quot;Resource Hours" = Average number of hours per Room per Day routinely scheduled to be available for performance of procedures. (Example: 2 rooms @ 8 hours per day <u>plus</u> 2 rooms @ 10 hours per day <u>equals</u> 36 hours per day; <u>divided</u> by 4 rooms <u>equals</u> an average of 9 hours / per room / per day.)

d) Surgical Specialty - Of the cases in <u>Surgical Operating Rooms</u> (Item 8.a.[1]), enter the number of <u>cases</u> by surgical specialty area in the chart below:

Specialty Area	Inpatient Cases	Ambulatory Cases
Cesarean Sections	1,194	
Cystoscopy	164	602
Endoscopy (all endo types performed in Surgical Operating Room)	10	15
General	2,211	2,739
Gynecology	534	1,607
Neurosurgery	705	700
Open Heart	981	*1
Ophthalmology	1	764
Oral Surgery	42	1,085
Orthopedics	1,771	2,557
Otolaryngology	316	2,227
Plastic Surgery	99	259
Podiatry	0	207
Thoracic (other than open heart)	476	9
Urology	337	826
Other (Specify) (Vascular)	294	33
Total Surgical Operating Room Cases (Totals should equal totals 8, a[1], columns D & E)	9,135	13,630

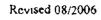
Revised 08/2006 Page 9

<sup>\*\* &</sup>quot;Case Time" = Time from Room Set-up Start to Room Clean-up Finish. Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. <u>NOTE</u>: This definition includes all of the time for which a given procedure requires an OR/PR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure. For purposes of scheduling and efficiency analysis, this definition is ideal because it includes all of the time that an OR/PR must be reserved for a given procedure.

## 9. Non-Gastrointestinal Procedure Rooms and Cases WAKEMED RALEIGH ALL SITES

Please report only rooms or cases not reported in 8a or 8b: Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of procedures other than gastrointestinal endoscopy. (Do not list a room for more than one use). Please note: Any procedures performed in these rooms should not be billed as having occurred in an operating room or reported in 8 as procedures performed in an operating room. Cases: Count each patient as one case regardless of the number of procedures performed while patient was in the room.

Use	Number of Rooms	Inpatient Cases	Ambulatory Cases
Cast Procedures			_
Cystoscopy			
Endoscopies (other than GI Endoscoptes) unless they were performed in a surgical operating room			
Lithotripsy	0		0
Special Procedures/Angiography (neuro & vascular but not including cardiac cath.)	3	9,158	9,346
Sutures			
YAG Laser			
Other (Specify) Minor Procedure	1		294
Totals	4	9,158	9,640



North Carolina Department of Health and Human Services Division of Facility Services Acute and Home Care Licensure and Certification Section 1205 Umstead Drive, 2712 Mail Service Center

Raleigh, North Carolina 27699-2712

Telephone: (919) 855-4620 Fax: (919) 715-3073

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License # H0238 Computer: 923421 PC \_\_\_\_\_\_\_

Date 12-6-06

Medicare # 340073

License Fee:

\$2,775.00

## 2007 HOSPITAL LICENSE RENEWAL APPLICATION

		: Duke University I tion, partnership, ind			wning the	enterprise or service	:e.)
Doing Busin (d/b/a) name		h the facility or servi	ces are advertised o	or presente	d to the pu	blic:	
PRIMARY: Other: Other:	DHRH S	ralitix Raleisix Hasni Sports Medicine and a Pharmacist	<b>itel</b> Duke f Physical Therapy	Raleigh	Hospita	11	
Facility Ma	iling Address:	3400 Wake Forest Raleigh, NC	Road 27611-8280				
Facility Site County: Telephone: Fax:		3400 Wake Forest Raleigh, NC 276 Wake (919)954-3000 (919)954-3900					
Title: CEO		J養納8家民物資為於 - esponsible to the governi	Douglas B. Ving body (owner) for th		nt of the lice	nsed facility)	
		Douglas B. Viesponsible to the governing				E 0 assed facility)	
Name of the	e person to cont	act for any questions	regarding this form	n:			
Name:	Richard	J. Gannotta, C	.00	Te	lephone:	954-3101	
E-Mail:	Rick.Ga	nnotta@duke.ed	<u> </u>	<u> </u>	_		
						5 06 75.00	•

"The N.C. Department of Health and Human Services does not discriminate on the basis of race, color, national origin, remotin, age, or charbility in employment or the provision of services."

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

License No: H0238

Facility ID: 923421

#### 8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

#### a) Surgical Operating Rooms and Cases

[1] Please report <u>Surgical Operating Rooms</u> built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals and COPY this sheet and Submit a duplicate of this page for each campus.

(Campus - If multiple sites:	 )

Type of Room [A]	Number of Rooms	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases	Ambulatory Cases [E]
Dedicated Open Heart Surgery (from 7b)	0	0	0	(-)
Dedicated C-Section - See addendum	1	1	120	
Other Dedicated Inpatient Surgery	Ō	0	0	
Dedicated Ambulatory Surgery	0	0		
Shared - Inpatient / Ambulatory Surgery	12	0	2366	8155
Total of Surgical Operating Rooms & Cases (Columns [D] & [E] should equal Totals in 8(d))	13	1	2486	8155

[2] Does this facility have <u>additional surgical operating rooms</u> (i.e., <u>not</u> listed above) <u>that</u> to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714?	t are being developed pursuant
If "Yes," please list the Types of Rooms and Number of Rooms being developed:	

#### b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of <u>Gastrointestinal Endoscopy Rooms</u> and the number of cases performed in these rooms during the reporting period. (<u>NOTE</u>: <u>Other procedure rooms</u> should be included in <u>Section 9</u> on <u>Page 10</u> of this application.) Count <u>each patient as one case</u> regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room	Number Of Rooms	Of the Rooms in Column [B], the number "Not in Use"	Inpatient Cases	Ambulatory Cases	Total Number of Procedures
[A]	(B)	[C]	(D)	[E]	<b>[F</b> ]
Gastrointestinal Endoscopy Rooms & Cases			GI:342	<sup>GI:</sup> 5281	GI: 6885
	3	0	Non GI: 35	Non GI; 138	Non GI: 211

	 100	<u> </u>
[2] Does this facility have <u>additional Gastrointestinal Endosci</u> <u>developed</u> pursuant to a Certificate of Need or pursuant to the Senate Bill 714?		
If "Yes," please list the Number of Rooms being developed:	res	_ <u>X</u> No
Revised 08/2006	 	Page 8

## Addendum to Page 8

Type of Room Column A Line 2

Dedicated C-Section room was closed and converted to a shared OR room on December 1, 2005

# 8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases continued

### c) Average Room Availability and Average Case Times:

Type of Room	"Resource Hours" * (Average <u>Hours</u> per Room per Day Routinely Scheduled for Use)	Average "Case Time" ** In Minutes for Inpatient Cases	Average "Case Time" ** in <u>Minutes</u> for Ambulatory Cases
Surgical Operating Rooms	10	171	72
Gastrointestinal Endoscopy Rooms	8.0	50	38

- \* "Resource Hours" = Average number of hours per Room per Day routinely scheduled to be available for performance of procedures. (Example: 2 rooms @ 8 hours per day <u>plus</u> 2 rooms @ 10 hours per day <u>equals</u> 36 hours per day; <u>divided</u> by 4 rooms <u>equals</u> an average of 9 hours / per room / per day.)
- \*\* "Case Time" = Time from Room Set-up Start to Room Clean-up Finish. Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. <u>NOTE</u>: This definition includes all of the time for which a given procedure requires an OR/PR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure. For purposes of scheduling and efficiency analysis, this definition is ideal because it includes all of the time that an OR/PR must be reserved for a given procedure.
- d) Surgical Specialty Of the cases in <u>Surgical Operating Rooms</u> (Item 8.a.[1]), enter the number of <u>cases</u> by surgical specialty area in the chart below:

Specialty Area	Inpatient Cases	Ambulatory Cases
Cesarean Sections	120	
Cystoscopy	0	0
Endoscopy (all endo types performed in Surgical		
Operating Room)	7	41
General	866	2651
Gynecology	185	314
Neurosurgery	141	192
Open Heart	0	
Ophthalmology	5	547
Oral Surgery	8	9
Orthopedics	1107	3962
Otolaryngology	0	0
Plastic Surgery		337
Podiatry	0	1
Thoracic (other than open heart)		0
Urology	38	101
Other (Specify)	Y Y	
Total Surgical Operating Room Cases (Totals should equal totals 8.a[1], columns D & E)	2486	8155

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Page 9

License No: H0238

Facility ID: 923421

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

#### 9. Non-Gastrointestinal Procedure Rooms and Cases

Please report only rooms or cases not reported in 8a or 8b: Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of procedures other than gastrointestinal endoscopy. (Do not list a room for more than one use). Please note: Any procedures performed in these rooms should not be billed as having occurred in an operating room or reported in 8 as procedures performed in an operating room. Cases: Count each patient as one case regardless of the number of procedures performed while patient was in the room.

Use	Number of Rooms	Inpatient Cases	Ambulatory Cases
Cast Procedures	0	0	0
Cystoscopy	1	30	190
Endoscopies (other than GI Endoscopies) unless they were performed in a surgical operating room	0	0	0
Lithotripsy	0	0	0
Special Procedures/Angiography (neuro & vascular but not including cardiac cath.)	1	263	393
Sutures	0	0	0
YAG Laser	0	0	0
Other (Specify) Pain Clinic	3	19	4825
Totals	5	312	5408

- \* Bronchoscopies performed in Endo room
- \*\* Includes consults and follow up visits Inpatient Ambulatory

Revised 08/2006

Page 10

# **Attachment 8**

Archives of Internal Medicine Vol. 165 No. 15, Aug 8/22, 2005

# The Burden of Staphylococcus aureus Infections on Hospitals in the United States

An Analysis of the 2000 and 2001 Nationwide Inpatient Sample Database

Gary A. Noskin, MD; Robert J. Rubin, MD; Jerome J. Schentag, PharmD; Jan Kluytmans, MD, PhD; Edwin C. Hedblom, PharmD; Maartje Smulders, MS, MPH; Elizabeth Lapetina, AB; Eric Gemmen, MA

Arch Intern Med. 2005;165:1756-1761.

**Background** Previous studies have investigated the impact of *Staphylococcus aureus* infections on individual hospitals, but to date, no study using nationally representative data has estimated this burden.

**Methods** This is a retrospective analysis of the 2000 and 2001 editions of the Agency for Healthcare Research and Quality's Nationwide Inpatient Sample database, which represents a stratified 20% sample of hospitals in the United States. All inpatient discharge data from 994 hospitals in 28 states during 2000 and from 986 hospitals in 33 states during 2001, representing approximately 14 million inpatient stays, were analyzed to determine the association of *S aureus* infections with length of stay, total charges, and in-hospital mortality.

**Results** Staphylococcus aureus infection was reported as a discharge diagnosis for 0.8% of all hospital inpatients, or 292 045 stays per year. Inpatients with S aureus infection had, on average, 3 times the length of hospital stay (14.3 vs 4.5 days; P<.001), 3 times the total charges (\$48 824 vs \$14 141; P<.001), and 5 times the risk of in-hospital death (11.2% vs 2.3%; P<.001) than inpatients without this infection. Even when controlling for hospital fixed effects and for patient differences in diagnosis-related groups, age, sex, race, and comorbidities, the differences in mean length of stay, total charges, and mortality were significantly higher for hospitalizations associated with S aureus.

**Conclusions** Staphylococcus aureus infections represent a considerable burden to US hospitals, particularly among high-risk patient populations. The potential benefits to hospitals in terms of reduced use of resources and costs as well as improved outcomes from preventing S aureus infections are significant.

Author Affiliations: Department of Medicine, Division of Infectious Diseases, Feinberg School of Medicine, Northwestern University, and Northwestern Memorial Hospital, Chicago, III (Dr Noskin); Department of Medicine, Division of Nephrology and Hypertension, Georgetown University, Washington, DC (Dr Rubin); School of Pharmacy, University of Buffalo, Buffalo, NY (Dr Schentag); Laboratory of Microbiology and Infection Control, Amphia Hospital, Breda, the Netherlands (Dr Kluytmans); 3M Medical Division, St Paul, Minn (Dr Hedblom); and Quintiles Strategic Research Services, Falls Church, Va (Mss Smulders and Lapetina and Mr Gemmen).

# **Data Show Scourge of Hospital Infections**

By Ceci Connolly Washington Post Staff Writer Wednesday, July 13, 2005; A01

Nearly 12,000 Pennsylvanians contracted infections during a hospital stay in 2004, costing an extra \$2 billion in care and at least 1,500 preventable deaths, according to state figures released yesterday that officials say represent a conservative measure of one of the deadliest problems in modern medicine.

As the first state to collect data on hospital-acquired infections, Pennsylvania has put hard numbers on a troubling phenomenon that until now has only been estimated. Even so, the true infection rate and cost is probably much higher, the report's authors said, because of underreporting by many hospitals. The actual tally could be as high as 115,000 infections, based on billing claims the hospitals submitted to insurers, the report said.

"Pennsylvania is 4 percent of the population, which means you may have an additional 100 people dying per day" nationwide because of hospital-acquired infections, said Marc P. Volavka, executive director of the Pennsylvania Health Care Cost Containment Council, the agency that issued the report. "That comes to an additional \$50 billion" in medical charges in the United States annually, he said.

As health care spending has skyrocketed, employers, which often pay the bills, have begun pressing hospitals to work to reduce a variety of mistakes -- from incorrect medications to avoidable infections -- to improve care and reduce costs. As part of that effort, Pennsylvania began last year to require every acute care hospital to report the number of infections contracted in the hospital in four major categories: surgical, bloodstream, pneumonia and urinary tract.

The mortality rate was highest -- 32 percent -- for patients who developed pneumonia while using a ventilator. The most common were urinary tract infections transmitted to patients using a catheter. The average cost to treat a Pennsylvania hospital patient who developed an infection was \$29,000, compared with \$8,300 for those who did not, the report found.

"Each quarter, the number of reported infections went up, and that trend we believe will continue in 2005 as more and more hospitals realize they need to come into compliance," Volavka said.

Nationally, the Centers for Disease Control and Prevention in Atlanta has estimated that as many as 2 million infections are acquired in hospitals each year, resulting in 90,000 deaths, said Denise Cardo, director of the Division of Healthcare Quality Promotion.

"This is terrible and this is not new," she said. "There are many more things we need to do in terms of preventing those infections, not just counting them."

Hospital executives cautioned that they are still working out the kinks in the data collection, and stressed that many efforts are underway to reduce preventable infections and other errors.

"Can we do better? Absolutely," said Elliot J. Sussman, president and chief executive of Lehigh Valley Hospital and Health Network in Allentown, Pa. "And this report can be a stimulus to do so."

Sussman, who has been a leader in the safety movement, said it is "ridiculous" to read that 16 hospitals reported not a single infection.

In Seattle, Michael Westley, medical director of the critical eare unit at Virginia Mason Medical Center, is leading an effort to reduce ventilator-associated pneumonia cases through simple steps such as keeping the patient's head elevated and ensuring the patient breathes independently for at least a few minutes each day.

"If you do those things and you do them every day, the experience has been the numbers of those infections go down," he said. "While our hospitals in general are safe, they could be even safer by routinely employing low-tech interventions."

Westley and other experts say the simplest remedy is hand-washing. Another common but preventable risk is caused by shaving an area prior to surgery, a procedure that creates abrasions that can become easily infected. The preferred technique is clipping hair.

In Pennsylvania, state officials and industry executives haggled over the numbers, particularly the report's estimate that the tally of hospital-acquired infections may be as high as 115,000.

"We think that's remarkably high," said Carolyn F. Scanlan, head of the Hospital and Healthsystem Association of Pennsylvania. She said many of the infections that hospitals billed for may have been acquired before admission.

Volavka, however, said his staff, working with infectious-disease specialists, screened out the infections most likely to have occurred before a patient arrived at the hospital.

Either the true number of hospital-acquired infections is much higher than 12,000 or hospitals are charging for infections that do not exist, said Kitty Gallagher, president of the Lehigh Valley Business Conference on Health Care and a member of the state commission. "Either way you look at it, the employers are paying for these infections."

Several other states, including Virginia, have passed laws requiring similar reporting by hospitals. Thirty states, including Maryland, are considering similar legislation but do not currently collect data on hospital-acquired infections.

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# 1.2 Million U.S. Patients Get Resistant Staph Each Year

Basic infection control can help stop the deadly bug, experts say

By Steven Reinberg HealthDay Reporter

MONDAY, June 25 (HealthDay News) — As many as 1.2 million U.S. hospital patients may be infected each year with a virulent staph infection that's resistant to antibiotics — a rate almost 10 times greater than previous estimates, a new study finds.

The research, conducted by the Association for Professionals in Infection Control and Epidemiology, also found that as many as 119,000 hospital patients each year may die from the tough to-treat strain of bacterium, called methicillin-resistant *Staphylococcus aureus* (MRSA). The germ is spread by touch and can lead to dangerous skin infections, blood infections and pneumonia.

"This is a wakeup call that hospital administrators should understand the importance of this problem," said report author Dr. William Jarvis, an epidemiologist and president of the consulting firm, Jason and Jarvis Associates.

The rate of MRSA was higher than previously been estimated, Jarvis said. "Not only did we find MRSA in all states in all facilities, but 66 percent of it was on the medical service, which runs counter to previous beliefs that most MRSA was in intensive care units," he added.

One expert agreed that more needs to be done to fight this looming threat.

"In the early years of the 21st century, we are seeing the value of antibiotics decline as more and more germs become resistant to them," said Dr. David Katz, the director of the Prevention Research Center at Yale University School of Medicine. "Methicillin resistant *Staph aureus* is one important example of this trend," he said.

The findings were based on surveys sent to 10,000 nurses, doctors, and other infection-control practitioners and included data on almost 8,000 infected patients from every state. More than 1,200 health care facilities + 21 percent of the nation's total -- were included in the survey.

The researchers found that 46.3 of every 1,000 patients had active MRSA, which is eight to 11 times higher that previously estimated.

The report, the National Prevalence Study of Methicillin-Resistant Staphylococcus aureus (MRSA) in U.S. Healthcare Facilities, was released Monday.

In contrast, one 2005 study, by the U.S. Centers for Disease Control and Prevention, estimated the MRSA infection rate at about 3.9 per 1,000 patients.

"Patients need to be aware of their risk of infection," said Kathy Warye, chief executive officer of the Association for Professionals in Infection Control and Epidemiology, which sponsored the study.

"If they have any underlying disease, such as diabetes or a heart condition, and it is likely they will be going

into a health care facility, they should speak with their physician about the risks they may be encountering," Warye said.

In addition, patients need to be assertive in making sure that the staff follows proper infection control procedures, Warye said.

Jarvis said that basic steps can be taken to curb the rising rate of infection.

First, patients who are most at risk for MRSA need to be identified and tested, he said. Patients who are infected need to be placed in isolation. In addition, health care workers need to follow proper procedures to prevent the spread of MRSA, including washing their hands and disinfecting the environment around the patient.

"Indiscriminate use of antibiotics in both hospitalized and outpatients is part of this problem," Katz added.
"So is failure by patients to complete courses of antibiotics as prescribed. And perhaps an even greater influence is the widespread use of antibiotics in feed animals," which also creates resistant strains, he said.

"Having advanced medicine with the introduction of antibiotics, we cannot let it regress by allowing the drugs to become useless. Policies to curtail the spread of resistant germs are urgently needed," Katz said.

#### More information

For more information on MRSA, visit the U.S. Centers for Disease Control and Prevention.

SOURCES: Kathy Warye, chief executive officer, Association for Professionals in Infection Control and Epidemiology, Washington, D.C.; William Jarvis, M.D., president, Jason and Jarvis Associates, Hilton Head Island, S.C.; David Katz, M.D., M.P.H., director, Prevention Research Center, Yale University School of Medicine, New Haven, Conn.; June 25, 2007, report, National Prevalence Study of Methicillin-Resistant Staphylococcus aureus (MRSA) in U.S. Healthcare Facilities

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# Attachment 9

ORTHOPAEDIC SURGEONS STEPHEN P. MONTGOMERY, M.D. on the ideas

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JOHN B. CHIAVETTA, M.D. GORDAN PARAMETERS

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**EXECUTIVE DIRECTOR** KARL F. STEIN

RETIRED

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MAILING ADDRESS

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PHONE: (919) 781-5600 APPOINTMENTS: (919) 863-6808 www.raleighortho.com

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RALEIGH ORTHOPAEDIC

July 23, 2007

Mr. Robert J. Fitzgerald, Director NC Division of Health Service Regulation 2701 Mail Service Center Raleigh, NC 27699-2701

Charity Care Analysis for Same Day Surgery Performed at Wake RE: County Facilities

Dear Mr. Fitzgerald,

Raleigh Orthopaedic Clinic, PA intends to submit a petition for an adjusted need determination for six orthopedic ambulatory surgery operating rooms in Wake County. This letter documents the commitment of Raleigh Orthopaedic Clinic, PA to improve access to ambulatory surgery for all patients and to provide charity care.

The chart below summarizes the numbers and percentages of charity care cases reported in the 2007 License Renewal applications data submitted by Wake County hospitals and ambulatory surgery centers. (The license forms use the terms "same day surgery" instead of ambulatory surgery.)

		Total # of	
License Renewal Applications - 2005- 2006 Reporting Period	# Reported	Reported	Charity %
	· ·	Same Day	of Total
	Same Day	Surgery	Same Day
	Surgery	Cases (All	Surgery
	Cases	Payors)	Case <u>s</u>
Duke Raleigh Hospital	85	8,155	1.04%
WakeMed Raleigh Campus All Sites	981	18,408	5.33%
WakeMed Cary	159	13,269	0.86%
	517	18,222	2.84%
Rex - All locations	1 -	6,717	0.01%
HealthSouth	0	787	0.00%
Raleigh Plastic Surgery	0	587	0.00%
Southern Eye Associates Totals	1,743	66,145	2.6%

As seen above, not all facilities provided access for charity care patients. Based on the analysis above, it is clear that the citizens of Wake County lack appropriate access to ambulatory surgery facilities that are willing to provide charity care access

Raleigh Orthopaedic Clinic recognizes an opportunity to make positive changes and improve access for all patient payor categories. We are convinced that an orthopedic ambulatory surgery center that provides charity care would be of great benefit to Wake County.

If operating room need determinations are included in the State Medical Facilities Plan, the issue of improving charity care patient access should be addressed through changes in the regulatory criteria in 10A NCAC 14C .2100. Raleigh Orthopaedic Clinic suggests the following additional standards to be added to the criteria:

The applicant is required to demonstrate that the utilization is reasonably projected to include percentages of charity care cases at or above the average of all existing surgery providers in the service area.

The applicant shall provide a description of strategies and activities that will ensure access and utilization by indigent patients.

Please accept this letter as a written commitment that ROC surgeons are strongly committed to provide charity care in a dedicated orthopedic ambulatory surgery center to meet or exceed the average percentages of the existing surgery facilities. ROC surgeons intend for this charity care commitment for a proposed ambulatory surgery facility would be in addition to the charity care professional fees.

Please contact me if you have questions regarding the suggested changes to 10A NCAC 14C .2100 criteria and standards for surgical services and operating rooms.

Sincerely.

Karl Stein

**Executive Director** 

Cc: Sandra B. Greene, DrPH

725 Airport Road Chapel Hill, NC 27599

## **Attachment 10**

RE: Raleigh Orthopaedic Clinic Petition for Dedicated Orthopedic Ambulatory Operating Rooms

Dear Mr. Stein,

I am writing in support of the ROC petition that seeks an adjusted need determination for six orthopedic ambulatory operating rooms to be allocated to Wake County in the 2008 State Medical Facility Plan. Patient safety will be enhanced by increasing the availability of ambulatory operating rooms.

Please recognize that adverse events are common in hospitals. Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively.\(^1\) These studies were the impetus for the landmark report of the Institute of Medicine, To Err is Human.

Adverse events in ambulatory surgery centers appear to be less common. Two large separate studies looked at factors contributing to return hospital visits, hospital readmissions and prolonged stay after ambulatory surgery performed at a major ambulatory surgery center in Toronto.<sup>2</sup> The researchers found that of 17,638 consecutive patients having ambulatory surgery, 193 readmissions occurred within thirty days (readmission rate of 1.1 percent). The complication rate was a very low 1.5 percent.

Ambulatory surgery centers have a lower incidence of wound infections. A comparative study by Miller et al. of surgical site infections (SSI) in inpatient and ambulatory surgery settings found that the SSI rate in ambulatory surgery was only about 35 percent of that in inpatient settings and 38 percent of that in a "mixed" group. These differences are quite large, and were not explained by risk adjustment for severity of condition or by differences in patient populations. This raises the possibility that for some conditions and procedures—such as those that expose the patient to risks of surgical infections—the ambulatory setting may be safer.

Accreditation requires a surgery center to have extensive safety policies and procedures. Accrediting agencies include the Joint Commission for Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), and the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF). Good public policy would encourage all surgery centers to become accredited and licensed.

North Carolina regulations prohibit the licensure and accreditation of many surgery centers. The state has a two-tiered system of surgery centers; licensed, accredited surgery centers are subject to CON regulation, which severely limits their number. Office-based surgery centers are not subject to CON regulation. They are subject to Medical Board safety guidelines but are prohibited by the Division of Facilities Services from seeking licensure or accreditation.

The CON program's restrictive "need formulas" have forced surgery out of the accreditation system and thereby have worked against public safety. Single-specialty physician-controlled surgery centers should be able to obtain a CON without being subject to a need formula. Increased patient safety would result because the centers could then become licensed and accredited.

In conclusion, patient safety will be enhanced by making Certificates of Need for ambulatory operating rooms more available.

Sincerely,

Hadley Callaway, MD

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References

- 1. Brennan, Troyen A.; Leape, Lucian L.; Laird, Nan M., et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. N Engl J Med. 324:370376, 1991. See also: Leape, Lucian L.; Brennan, Troyen A.; Laird, Nan M., et al. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. N Engl J Med. 324(6):377384, 1991. See also: Thomas, Eric J.; Studdert, David M.; Burstin, Helen R., et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. Med Care forthcoming Spring 2000.
- 2. Mezei G. and Chung F. Return hospital visits and hospital readmission after ambulatory surgery. *Annals of Surgery* 230(5):721-7, 1999.
- 3. Miller K, Martin D, Gustafson T. Differences between inpatient and ambulatory surgical site infection rates are not explained by risk adjustment. *Infection Control and Hospital Epidemiology* February 2000.





July 26, 2007

Mr. Karl Stein Raleigh Orthopaedic Clinic 3515 Glenwood Avenue Raleigh, NC 27612

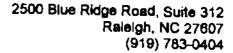
RE: Raleigh Orthopaedic Clinic Petition for Dedicated Orthopedic Ambulatory Operating Rooms

Dear Mr. Stein,

I am writing to express my support of the ROC petition that seeks an adjusted need determination for six orthopedic ambulatory operating rooms to be allocated to Wake County in the 2008 State Medical Facility Plan. As the Division Director for Bayada Nurses, I have frequent contact with numerous healthcare professionals in Wake County.

The tremendous population growth for Wake County will create much greater need for healthcare resources than other ereas of the state. I was surprised to learn that Wake County has a scarcity of operating rooms and thousands of Wake County ambulatory surgery patients left their home county to obtain surgical procedures. Your petition offers a valid alternative to improve competition, reduce healthcare costs and expand patient choice. Please let me know if I can provide additional support.

Sincerely





July 27, 2007

Mr. Karl Stein Raleigh Orthopaedic Clinic 3515 Glenwood Avenue Raleigh, North Carolina 27612

RE: Support for Raleigh Orthopaedic Clinic's petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

Dear Mr. Stein:

I am writing in my capacity as Director, Project Access of Wake County to support the petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms in Wake County. Raleigh Orthopaedic Clinic physicians have lead the county's orthopedic community in providing medical and surgical care, including substantial uncompensated indigent care coverage in association with the Project Access volunteer physician program.

Since 2001, Raleigh Orthopaedic Clinic physicians have provided approximately \$800,000 of uncompensated care to indigent citizens in our community associated with the Project Access Program.

It is not enough to say "thank you" Raleigh Orthopaedic Clinic for the almost unlimited donated care. Rather I want to say thank you by offering this unrestricted endorsement of your expansion plans that the whole community might benefit from the expanded care capacity.

Sincerely,

Paul Harrison, Director

Haus Hurrison /mat

Project Access Manager

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

Dear Mr. Stein:

I am writing in support of your petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms in Wake County. Raleigh Orthopaedic Clinic physicians provide an extensive array of surgical patient care including indigent care and uncompensated emergency department coverage. Key factors that support the proposal include:

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Sincerely.

FLEISHMAN HILLARD

Flenhman-Hälard Inc. 4350 Lassiter at North Hills Ave. Suite 260 Raleigh, NC 27609 Tel: 919-457-0744 Ccll: 919-559-5679

Britt W. Carter Senior Vice President and General Manager

Aug 919-457 0741 britt carter@fleishman.com www.fleishman.com

RE:

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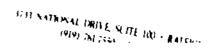
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Ana Daing



FINA M. GOERTT, CPA



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Sincerely,

PRESIDENT

FILLER STRATEGIES

Fulcrum Strategies

Ron Howilgon

Phone: 818 753 4141 P. fax: 519.639.6303 P.D. Box 469 + Garner, NC 27529-4-4-7



July 24, 2007

Mr. Karl Stein Raleigh Orthopsedic Clinic 3515 Glerwood Avenue Raleigh, NC 27612

RE:

Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

Dear Mr. Stein:

I am writing in support of your petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms in Walke County. Raleigh Orthopsedic Clinic physicians provide an extensive array of surgical patient care including indigent care and uncompensated emergency department coverage. Key factors that support the proposal include:

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Sincerely.

George DeLoache, President

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Sincerely,

Both Fon Ward 13al Deenhurst Br. Raleigh, N.C. 27614

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EDITH R. MOGLE, CPA

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Sincerely.

Same S. Conte p. CPA



JAMES E. CARTER, JR., CPA

Heather L. Drake, CPA



Certified Public Accountants Hughes Pittman & Gupton, LLP +500 Sunday Drive, Suite 300 Raleigh, North Carolina 27607

919,232,5957 direct 919,787,9765 main 919,787,9384 fax

www.hpgcpas.com hidrake@hpgcpas.com



Raleigh, NC 27612

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Heatherd Grave

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Sincerely,

Nalta Hicks Hunt

26 July Of



W. Skelle Hunt III ~ Project Manager Historic Preservation Division

Mell: P.O. Bex 260

Hendquarters: 716-634-3967

Buffale, NY 14231-9260 Office: #25 (Hysternill Ditter 5 TSI Reserve Dy Fax: 716-634-3983

1-800-828-1446

Wilmington, NC 25489

N. Carolina Office: 918-358-0339 Cell: 973-819-6789

www.internationalchimney.com

Raleigh Orthopaedic Clinic Petition for a special need determination for six RE: (6) dedicated orthopedic ambulatory operating rooms

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Sincerely,

8544 WOLVERTON FIELDS Dr. WALE FOREST NO 27587

RE: Raleigh Orthopædic Clinic Petition for a special need determination for six (6) dedicated orthopædic ambulatory operating rooms

Dear Mr. Stein:

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Sincerely,

Eric W. Schmidt

Winfield & Associator marketing & Adult

Eric Schmidt

PRESIDENT

WINFIELD& associates

3221 Blub Fickin Food Sale 18 Park 19 Park 19

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W.B.CH PODONE

W. Nich Redding, DVNI, NS, DACYS Cirecal Associate Professor Eguine Orthopudes and Lameness

NC STATE

Department of Clinical Sciences College of Victoriaary Medicine 4700 Hillsborough Street Rateigh, NC 27606

919.513.6786 (Office) 919.513.6717 Fax) 919.513.6630 (Course Surgery Service) rich\_redding@rcau 8du

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Rendy Southerland

PEACHTREE MARKET 7400-7 Six Forks Rd.

Shear Alternatives 🛚

Raleigh, NC 27815 (919) 848-1968

Date:	Time:

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JANON CFF

Sincerety

Jonathan S. Phillips, CFP" First Vice President Investments

WACHOVIA SECURITIES

Wachovia Securities, LLC

8540 Colonnade Center Dine, Sijte []] Rakuen, NC 27615 3052

Raleigh, NC 27615 3052 Tel 919 841 5360 Fax 919 841 5410 800 462 3939 Jonathan, s. philipsathanch

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Park D. Mily

Charles B. McBrayer
First Vice President - Investments
Quantum Portfolio Manager

WACHOVIA SECURITUES

Wachovia Securities, LLC 8540 Colonnade Center Drive, Suite 101 Raleum, NC 27615 Tel 919 841 5400, 919 841 5359 Fax 919 841 5410 800 462 3939 charles.mcbrayer@wwchona

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## Hutchison Law Group

Mr. Karl Stein Raleigh Orthopaedic Clinic 3515 Glenwood Avenue Raleigh, NC 27612

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Fred D. Hutchison

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Willay & Offins 3300 APACHE DR. RALEIGH, N.C. 27(09

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Pal. NC 27604

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Konall & Hames

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Popula a. Dithe 2023 Camera Sans Dine Cay, NL 27579

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1009 Marilyn Dr.

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Nachel C. Baker 104 11. Ellington St. User. M.C. 27502

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Donie Huce 102 Satterwhite Dr. Knightdale NC 27545

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Glizabeth Walle 312 Hunter St. Cary MC 27511

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Kozarna Dudla, 5400 Alpine Drine Kalaigh, NC 21609

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1911 OAK ESPATES ST. Apt. 1118
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7245 hullang 7245 hunor Oaks Drine Raleign N.C. 27615

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5416 Shadowbrook Dr.

Raleigh, NC 276/2

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Choistha MADIMA

1913 Kudrowhane

Mornsville, LIC 27560

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7905 Ridge Bints Lome Pareish M 2765

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217 N MAIN 5T

FRANKLINTON, NC 27525

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Whitakers NC 27891

Philip M. Roberts 154 Adcock Rd

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John D Lyav, Jo 203 Couper Dr Raleish, Ne 27608

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Susan L. Murda Accounts Partable

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am L

WILLIAMS
REALTY & BUILDING
COMPANY, INC.

J. Cross Williams Jr.

cross (a) harbro, com

37/1 Sienwood Avanue, Raleigh, NC 27612 PC Box 18271, Raleigh, NC 27619 wibro rom

919 781 7107 Office 919 787 2316 Fax 919 427.1257 Mobile

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Jam Matter! (el Lugaro lone meddlesex, NC

27557

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MARK MATTSON

1207 KEMBOLFON Da

CARY WC 27511

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Light Ruba 1629 Air Park Drive Apex, nc 27523

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Tucy M. Colobrai 704 Fairway Dr. Clayton, Nº 27520

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11300 Rung Hill Rd Raleigh, NC 27614

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531 Hickorywood Blud

Cary, NC 27519

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KEITH SACKSON KEITH SACKSON 4821 WATERFORD VILLAGE WAY RALEICH NC 27601

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112 Cromwell Ct.

Raleigh, NC 276, 4

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Thomas Earl Banville Martin à Jones Law Offices

7/23/07

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mark Ikims DDD 7505 Rainwater Rd. Rategr NC 27615

MM Leffins D.D.S.

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Hatts Carto CFP®

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Jana M. Mauring 1504 Pierce Office RD April No 27.539

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SSHY WOLVERTON FILLOS DO. WAKE FULL, NC 27 Have your Prake

8544 Wolveston Fields Dr

Wake Forest, NC 27587 919-740-5418 (Mobile) 919-342-0363 (Office) 866-898-8572 (Fax)

pleaning whavevourcakeonline com ww.haveyoureakconline.com

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1117 Harris Millet Roleigh, NC 2760

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Dr.
3405 Ingram Dr.
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Wake County citizens need to have improved access to licensed operating rooms and a choice of new providers for a freestanding ambulatory surgery center. Positive competition will encourage hospitals to expand their hours of surgical service and to focus on improving patient and physician satisfaction.

Sincerely,



ERNEST W. WARNER, JR., CPA



RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

Dear Mr. Stein:

I am writing in support of your petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms in Wake County. Raleigh Orthopaedic Clinic physicians provide an extensive array of surgical patient care including indigent care and uncompensated emergency department coverage. Key factors that support the proposal include:

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JOE KIMOSH

11300 KUMSHILL
RALEIGH 27614

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DIEN Wait 121 Donna Place Cary, NC 27513

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Dainy Sonders 2420 fall lone apt 105 Roleigh, m 27604

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Margarda Frankland 100 Stranavn Place Ralligh NX 27612

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Sincerely,

Edward L. Mood



FDWARD L. MOODY

Sherwood H. Smith, Jr. PD. Box 1551 Raieigh, North Carolina 27602 919-546-6382

July 27, 2007

Mr. Karl Stein Raleigh Orthopaedic Clinic 3515 Glenwood Avenuc Raleigh, North Carolina 27612

Re: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

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Mr. Karl Stein Page 2 July 27, 2007

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Herwood A. Swith, B.

Sincerely,

SHSJR:jw

Deborah Goeken Vice President Integrated Solutions

Cardinal Health 5104 Chin Page Road Durham, NC 27703 919 454 1156 main 919 468 1326 fax deborsh goskengsandhal com

Mr. Karl Stein Raleigh Orthopaedic Clinic 3515 Glenwood Avenue Raleigh, NC 27612



cardinalhealth com

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

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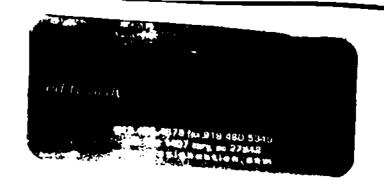
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Total R. CROSSE.
President, Crosse & Associales, Inc.
4513 Crecumour Rd. # 505

Rleigh, NC 27612

919-781-1811

JUL-31-07 01:47 PM

### F. 02

# Wendell H. Murphy Post Office Box 280 Rose Hill, North Carolina, 28458

July 31, 2007

Mr. Karl Stein Raleigh Orthopaedic Clinic 3515 Glenwood Avenue Raleigh, North Carolina 27612

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

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Mr. Karl Stein July 31, 2007 Page 2

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Sincerely

Wendell H. Murphy

Wendell Murphy

WHM/djm

## Raleigh Orthopaedic Clinic, PA

Petition for Need Determination for Six Orthopedic Ambulatory Surgery Operating
Rooms in Wake County

EXECUTIVE SUMMARY

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Facilities Plan and then holds public hearings and receives petitions for special need determinations for regulated healthcare services. Raleigh Orthopaedic Clinic (ROC) has serious concerns that the Proposed 2008 Plan includes no additional operating rooms for Wake County. In fact, no additional operating rooms have been allocated to Wake County by the Plans in over ten years.

Raleigh Orthopaedic Clinic petitions for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers in Wake County.

ROC physicians know that an orthopedic ambulatory surgery center (ASC) can offer patients exceptional quality and customer service, lower costs, more efficient scheduling and better teamwork. The American Academy of Orthopaedic Surgeons states "ASCs provide benefit to both patients and orthopaedic surgeons because many musculoskeletal surgical procedures can be provided in an efficient, cost effective manner. ASCs can improve the quality of care received by the patients and delivered by the physician."

The rationale for the ROC petition is summarized:

- Wake County has 9.93 operating rooms per 100,000 population, far less than comparable counties and 22 percent less than the statewide rate of 12.75 ORs per 100,000 persons.
- ASCs generally have greater scheduling efficiency and higher patient satisfaction as compared to hospitals. While 73 percent of all surgery cases are ambulatory. 89 percent of the operating rooms in Wake County are hospital-based.
- In 2006, over 6,000 Wake County patients obtained ambulatory surgery in another county; more ambulatory surgery patients left Wake County in 2006 as compared to Mecklenburg and Forsyth Counties.
- No dedicated orthopedic ambulatory surgery operating rooms exist in Wake County even though orthopedic ambulatory surgery procedures comprise 23 percent of the total outpatient cases.
- Orthopedic procedures performed in freestanding ambulatory surgery centers offer 30 to 40 percent lower charges and reimbursement rates.
- ROC physicians have already established exemplary records for providing charity care in their offices and at the area hospitals.

Approval of the petition will benefit the community by allowing new providers to compete and improve access to dedicated orthopedic ambulatory surgery operating rooms. The ASC will offer greater convenience, higher patient satisfaction and lower costs and charges. Like hospitals, the proposed ambulatory surgery center will be licensed, accredited and required to provide care to Medicare, Medicaid, insured patients and charity care patients.

REC'D @ Juy 24 2007 GREENVILE PUBLIC HEARING

Karl Stein, Executive Director Raleigh Orthopaedic Clinic DFS HEALTH Planning RECEIVED

Proposed 2008 State Medical Facilities Plan Public Hearing Presentation

Medical Facilities Planning Section

My name is Karl Stein. I am the Executive Director of Raleigh Orthopaedic Clinic. I am here today to speak about the shortage of operating rooms in Wake County.

Rapid population growth in Wake County has caused a shortage of operating rooms. This shortage causes delays and hardships for patients.

Raleigh Orthopaedic Clinic petitions for a special need determination for Wake County for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

The current OR methodology in the Proposed 2008 State Medical Facilities Plan does not accurately assess the ambulatory surgery operating room needs of Wake County. Shortcomings of the current OR methodology include:

- The State Medical Facilities Plan has not shown a need for operating rooms in Wake County for many years, despite the fastest population growth among NC counties and approximately 200,000 new county residents over ten years. We think this is implausible and conclude that the operating room need formula does not work correctly in the case of Wake County.
- Established providers have gained added new operating rooms and bypassed the CON process by exploiting toop holes in the regulations/law. new Certificates of Need through non-competitive channels, even though the current methodology showed no need. This has rendered the need formula irrelevant to established providers and unfairly blocks new providers from any hope of participation.
- The current methodology and CON process allow existing providers to add "minor procedure rooms" to perform surgical cases. These procedure rooms are not constructed or equipped to the same standards as licensed operating rooms. Shifting surgery cases from licensed operating rooms to the minor procedure rooms does not promote access to quality healthcare.
- Patients may not be aware these "minor procedure rooms" are nearly always billed out to patients and/or insurance companies at the same rate as the licensed ORs, nor do they meet the requirements of licensed ORs.
- The OR methodology is also inaccurate for Wake County because the

calculations include the **four** dedicated open heart operating rooms that are extremely underutilized, performing less than 40 percent capacity. If the volume of open heart cases and the four dedicated operating rooms were excluded from the methodology, the methodology would show a deficit operating rooms.

- The current methodology does not facilitate the growth of ambulatory surgery centers. In Wake County, hospitals generally have lower surgery scheduling efficiency and lower patient satisfaction as compared to ambulatory surgery centers.
- In this era of drug-resistant bacteria, surgical infections are a major concern for patients and surgeons. Ambulatory surgery centers have demonstrated much lower infection rates than hospitals for outpatient surgery, even after controlling for co-morbid conditions of patients.
- In 2006, over 6,000 Wake County patients had to leave Wake County to get their surgery. They had long commutes for surgery and follow-up visits. If they had a complication, a local doctor unfamiliar with the case had to see them in the emergency room. This is unsafe and unfair.
- There are no dedicated orthopedic operating rooms Wake County, even though orthopedics accounts for is 23 percent of all outpatient surgeries. We need dedicated orthopedic rooms with specialized surgical teams to provide top quality.
- Orthopedic procedures performed in freestanding ambulatory surgery centers
  offer substantially lower costs, charges and reimbursement for insured
  patients and Medicare and Medicaid programs. The cost to patients can be
  30 to 40 percent lower in non-hospital ambulatory surgery centers. This is
  especially important for patients with high-deductible insurance plans.

## CHNIC

Raleigh Orthopaedic physicians are leaders in providing charity care. We pledge to continue charity care in any new operating rooms.

Thank you for considering our petition for a special need determination for Wake County for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

REC'D & JULY 30, 2007 PUBLICHEARING IN WILMINGTON

Hadley Callaway, MD Orthopedic Surgeon Raleigh Orthopaedic Clinic DFS HEALTH PLANNING RECEIVED

JUL 3 0 2007

Public Hearing Presentation Proposed 2008 State Medical Facilities Plan Wilmington, NC, July 30, 2007

Medical Facilities
Planning Section

My name is Hadley Callaway. I am an orthopedic surgeon at Raleigh Orthopaedic Clinic. I am here today to speak about the shortage of operating rooms in Wake County.

Rapid population growth in Wake County has caused a shortage of operating rooms. This shortage causes delays and hardships for patients.

Raleigh Orthopaedic Clinic petitions for a special need determination for Wake County for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

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- 2. Established providers have gained added new operating rooms and by-passed the CON process by exploiting loop holes in the regulations/law. new Certificates of Need through non-competitive channels, even though the current methodology showed no need. This has rendered the need formula irrelevant to established providers and unfairly blocks new providers from any hope of participation. I hope you would agree that the unusual circumstance of no new provider having the opportunity even to apply for an operating room for ten years in the fastest-growing county of the state would merit an exemption to the need formula.
- 3. The current methodology and CON process have allowed existing providers in Wake County to add a substantial number of "minor procedure rooms" to perform surgical cases. These procedure rooms are not constructed or equipped to the same standards as licensed operating rooms. Shifting surgery cases from licensed operating rooms to the minor procedure rooms does not promote access to quality healthcare.
- 4. Patients may not be aware these "minor procedure rooms" are nearly always billed out to patients and/or insurance companies at the same rate as the licensed ORs, nor do they meet the requirements of licensed ORs.
- 5. The OR methodology is also inaccurate for Wake County because the calculations include the **four** dedicated open heart operating rooms that are

extremely underutilized, performing less than 40 percent capacity. If the volume of open heart cases and the four dedicated operating rooms were excluded from the methodology, the methodology would show a deficit operating rooms. Another hospital has cardiovascular operating rooms (in practice, although not listed so on the license renewal) which are also underutilized and could also be excluded.

- The current methodology does not facilitate the growth of ambulatory surgery centers. In Wake County, hospitals generally have lower surgery scheduling efficiency and lower patient satisfaction as compared to ambulatory surgery centers.
- 7. In this era of drug-resistant bacteria, surgical infections are a major concern for patients and surgeons. Ambulatory surgery centers have demonstrated much lower infection rates than hospitals for outpatient surgery, even after controlling for co-morbid conditions of patients.
- 8. In 2006, over 6,000 Wake County patients had to leave Wake County to get their surgery. They had long commutes for surgery and follow-up visits. It is unsafe for a family member to drive long distances in traffic while managing a sedated patient. If the patient had a complication, a local doctor unfamiliar with the case had to see them in the emergency room. This is unsafe and unfair, both for Wake County patients and Wake County physicians who are providing the emergency on-call coverage.
- There are no dedicated orthopedic operating rooms Wake County, even though orthopedics accounts for is 23 percent of all outpatient surgeries. We need dedicated orthopedic rooms with specialized surgical teams to provide top quality.
- 10. Orthopedic procedures performed in freestanding ambulatory surgery centers offer substantially lower costs, charges and reimbursement for insured patients and Medicare and Medicaid programs. The cost to patients can be 30 to 40 percent lower in non-hospital ambulatory surgery centers. This is especially important for patients with high-deductible insurance plans.

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DFS Health Planning RECEIVED

AUG 0 2 2007

Mr. Karl Stein Releigh Orthopsedic Clinic 3515 Glerwood Avenue Releigh, NC 27612

Medical Facilities Planning Section

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DFS HEALTH PLANNING RECEIVED

AUG 0 2 2007

Medical Facilities
Planning Section

Mr. Karl Stein Raieigh Orthopaedic Clinic 3515 Gienwood Avenue Raieigh, NC 27612

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Medical Facilities Planning Section

## DAIL PROPERTIES

July 31, 2007

Mr. Karl Stein

Raleigh Orthopaedic Clinic

3515 Glenwood Avenue

Raleigh, NC 27612

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Suction Stail

125 Timber Drive

(919) 779-7707

Garner, North Carolina 27529

FAX (919) 779-3547

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Medical Facilities Planning Section

RONALD A. BATCHELOR

Mr. Karl Stein Raleigh Orthopaedic Clinic 3515 Glenwood Avenue Releigh, NC 27612

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P.84

Wendell H. Murphy
Post Office Box 280

Rose Hill, North Carolina 28458

July 31, 2007

Mr. Karl Stein Raleigh Orthopaedic Clinic 3515 Glenwood Avenue Raleigh, North Carolina 27612

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DFS Health Planning RECEIVED

AUG 03 2007

Medical Facilities
Planning Section

AUG-01-07 08:25 AM

P.85

Mr. Karl Stein July 31, 2007 Page 2

Wake County citizens need to have improved access to licensed operating rooms and a choice of new providers for a freestanding ambulatory surgery center. Positive competition will encourage hospitals to expand their hours of surgical service and to focus on improving patient and physician satisfaction.

I should also note that Raleigh Orthopaedic serves many patients outside Wake County including my family. I sincerely hope that they receive approval for the requested six (6) orthopedic ambulatory operating rooms.

Smoerely

Wendell Murphy
Wendell H. Murphy

WHM/djm